NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE SCHERING-PLOUGH CORP. INTRON/TEMODAR CONSUMER CLASS ACTION,	: : :	Master File No. 2:06-cv-5774 (SRC)

OPINION

CHESLER, U.S.D.J.

This matter comes before the Court on motions to dismiss Plaintiffs' Consolidated Class Action Complaint ("the Complaint") filed by Defendants Schering-Plough Corporation, Schering Sales Corporation, Schering Corporation and Integrated Therapeutics Group, Inc. (collectively "Schering") [Docket Entry No. 124] and by Defendants Richard J. Kogan, William K. Heiden and Mary Naughton (collectively the "Individual Defendants") [Docket Entry No. 141]. For the reasons set forth below, the motions to dismiss will be granted by the Court.

FACTUAL BACKGROUND[1]

Plaintiffs[2] initiated this putative class action on December 1, 2006, alleging that

[1] Because the motions before the Court seek dismissal pursuant to Fed. R. Civ. P. 9(b), Fed. R. Civ. P. 12(b)(1) and Fed. R. Civ. P. 12(b)(6), only those facts relevant to determining the motions are recounted herein.

[2] The proposed class of health and welfare funds, third party payors ("TPPs") and consumers is represented by nine named plaintiffs: International Brotherhood of Teamsters Local No. 331 Health & Welfare Trust Fund, Heavy and General Laborers' Local Union 472/172 Welfare Fund, United American Insurance Company, Blue Cross Blue Shield of Alabama, Angela F. Montgomery, Harold Estelle, Beryl A'dare Bratton and Dorothy Bratton, and John Hutson, as putative personal representative of the Estate of John C. Hutson (collectively "Plaintiffs").

Defendants illegally marketed several prescription drugs for off-label use. Plaintiffs allege, on behalf of themselves and others similarly situated, that Defendants engaged in improper and illegal off-label promotion of Intron-A, PEG-Intron, Rebetol (the "Intron Franchise Drugs") and Temodar (collectively the "Subject Drugs")[3] in violation of: (1) the RICO Act, 18 U.S.C. § 1961, *et seq.* (Count I); (2) the New Jersey RICO Act, N.J. Stat. Ann. § 2C:41-1 *et seq.* (Count II); and (3) the New Jersey Consumer Fraud Act ("NJCFA"), N.J. Stat. Ann. § 56:8-1, *et seq.* (Count III). Plaintiffs also assert common law claims for unjust enrichment (Count IV), civil conspiracy (Count V), fraud (Count VI), negligent misrepresentation (Count VII), aiding and abetting breach of fiduciary duty (Count VIII) and equitable accounting (Count IX) based on Defendants' illicit marketing of the Subject Drugs. The basis of Plaintiffs' nine claims is fairly straightforward – they assert that Defendants orchestrated a campaign to illegally market and promote the Subject Drugs for off-label uses (i.e. uses not specifically approved by the Food & Drug Administration ("FDA")) and, as a result, Plaintiffs paid for drugs at an inflated price or for drugs they would not have purchased but for the illicit marketing scheme.

Defendant Schering-Plough Corporation is one of the world's largest manufacturers of pharmaceutical products. The Schering family of companies, including Defendants Schering-Plough Corporation, Schering Sales Corporation, Schering Corporation, and Integrated Therapeutics Group, Inc., manufactured, distributed, promoted, marketed and sold Temodar and

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[3] Plaintiffs seek to represent a proposed Class of health and welfare funds, TPPs and individual consumers "who have paid any portion of the purchase price for Intron Franchise Drugs [], and/or Temodar, Eulexin, Integrillin, and Fareston...." (Complaint ¶¶ 1, 269.) Yet, the allegations contained in the Complaint are limited to the off-label promotion and marketing of Temodar and the Intron Franchise Drugs. Plaintiffs make only passing references to Eulexin, Fareston and Integrillin. Therefore, the Court construes Plaintiffs' claims as if they are limited solely to the off-label promotion and marketing of Temodar and the Intron Franchise Drugs.

the Intron Franchise Drugs. In or about 1998, Defendants applied to the FDA for accelerated approval of Temodar for use in treatment of three forms of brain cancer: (i) refractory anaplastic astrocytoma, (ii) recurrent glioblastoma multiforme, and (iii) metastatic malignant melanoma. (Complaint ¶ 55.) In or about August, 1999, Temodar was approved by the FDA for the treatment of adult patients with refractory anaplastic astrocytoma. (Id. ¶ 57.) In March 2005, Temodar was approved for broader indications: (1) to treat adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment, and (2) to treat adult patients with refractory anaplastic astrocytoma. Previously, treatment of adults with refractory anaplastic astrocytoma was only approved on an accelerated basis. (Id. ¶ 58.) Defendants also sought FDA approval for the Intron Franchise Drugs, which include Intron A, a brand name drug generically known as interferon alfa-2b, recombinant, PEG- Intron, a branded drug known generically as Peginterferon alfa-2b, Rebetol, a branded drug known generically as ribavarin, and Rebetron, a brand name drug which is comprised of Rebetol and Intron A. (Id. ¶ 64.) Intron A has been approved to treat hair cell leukemia, follicular Non-Hodgkin's Lymphoma, condylomata acuminate and AIDS-related Kaposi's Sarcoma. The FDA has also approved Intron A for the treatment of chronic Hepatitis C in patients 18 years of age or older with compensated liver disease who have a history of blood or blood-product exposure and/or are HCV antibody positive, for the treatment of chronic Hepatitis B in patients one year of age or older with compensated liver disease, and as adjuvant to surgical treatment (within 56 days of surgery) for patients 18 years or older with malignant melanoma who are free of disease but at high risk for systemic recurrence. (Id. ¶ 66.) Peg Intron, a longer lasting form of Intron A, was approved by the FDA in 2001 for treating patients with compensated liver disease. (Id. ¶

68.) Rebetol has been approved by the FDA to treat Hepatitis C and Rebetron has been approved to treat the disease in patients with compensated liver disease. (Id. ¶¶ 67-68.)

The term "off-label" refers to the use of a prescription drug for any purposes – any indication, dosage form, dosage regimen, or population – not specifically approved by the FDA. Washington Legal Found. v. Henney, 202 F.3d 331, 332 (D.C. Cir. 2000). In order to secure approval by the FDA to market a drug for certain purposes, a manufacturer must demonstrate that the drug is safe and effective for those purposes for which it is being prescribed. See 21 U.S.C. § 355(d). The FDA approval process requires that a manufacturer submit to the FDA a portfolio of information including "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." Id. § 355(b)(1)(A). In addition, the manufacturer must provide the agency with proposed labeling to be included with the drug when it is distributed. Id. § 355(b)(1)(F). Any "false or misleading" statement in the labeling will render the drug misbranded, making distribution of the drug unlawful. See Id. § 352(a). In addition to regulating the labeling of prescription drugs, the FDA is also empowered under the FDCA to regulate prescription drug advertising and marketing, including marketing directed at physicians and the medical community at large. See 21 C.F.R. §§ 202, 203. Advertising or otherwise promoting a drug for off-label use is prohibited under the FDCA and its its implementing regulations. See 21 C.F.R. § 201.128 (intended use may be shown by the "labeling claims, advertising matter, or oral or written statements by such persons or their representatives"); 21 C.F.R. § 202. 1(e)(4)(i)(a) (advertising "shall not recommend or suggest any use that is not in the labeling"). The Act does permit drug manufacturers to disseminate marketing information concerning the safety and efficacy of off-label uses of prescription drugs,

but requires that the information may not be false or misleading or pose a significant risk to the public health. 21 U.S.C. § 360aaa-1(a)(2) Promotional activities subject to FDA regulations include advertisements, oral statements by the manufacturer or its representatives, and any other relevant source. Decision in Washington Legal Foundation v. Henney, 65 Fed. Reg. 14, 286-01 (Mar. 16, 2000).

On September 20, 2006, Defendant Schering Sales pled guilty to one count of criminal conspiracy to knowingly and willingly making false statements to the government, in violation of 18 U.S.C. § 371, in relation to the FDA's investigation of Defendant's alleged off-label marketing of Temodar and Intron A. See Amended Judgment, United States v. Schering Sales Corp., 06-CR-10250 (D. Mass. Feb. 7, 2007). The United States alleged that the Schering Sales business unit responsible for the sales and marketing of oncology drugs was engaged in widespread off-label marketing of Intron A for superficial bladder cancer and of Temodar for conditions other than refractory anaplastic astrocytoma. (Complaint ¶ 93.) The criminal charge to which Schering Sales pled guilty stemmed from Defendant's response to a letter from the FDA notifying Schering Sales that the FDA had identified various off-label promotional activities which violated the Federal Food, Drug and Cosmetic Act's prohibition on off-label promotion of drugs for unapproved indications. (Id. ¶ 92.) In response to the FDA's letter, Schering Sales stated that instances of off-label marketing were "isolated incident[s]" and were "certainly inconsistent with the direction provided by [Schering's] home office." (Id. ¶ 95.) In the Information charging Schering Sales with conspiracy to make false statements, the Government characterized Schering Sales's response letter as providing "false assurances designed to lull the FDA into believing that effective remedial action had been taken in order to avoid further FDA

scrutiny of Schering's promotional activity." (Id. ¶ 96.)

In their Complaint, Plaintiffs allege that Defendants marketed and promoted Temodar and the Intron Franchise Drugs for unapproved or off-label uses in violation of the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.* (Id. ¶ 116.) Specifically, Plaintiffs contend that Schering implemented the "Temodar 2000 Plan" and other marketing techniques in order to promote Temodar as an effective treatment for all types of gliomas and metastases, even though the FDA had not approved the drug for these conditions and/or Schering did not have clinical data to back up its claims regarding the effectiveness of Temodar for treating these conditions. (Id. ¶¶ 125-42.) Plaintiffs' cite the Temodar 2000 Plan, which called for, among other things, "expand[ing] use in non approved indications where data is either off label ... or not yet available...." (Id. ¶ 121.) They point out that Defendants promoted Temodar for off-label use for many conditions, including brain metastasis, certain types of gliomas, and anaplastic astrocytoma, even when the accepted Medical Compendia did not support such uses and where Schering "lack[ed] [] any data validating its safety and dosing." (Id. ¶¶ 127-28.) Moreover, Plaintiffs point out that Defendants' own internal documents conclude that Temodar had only a "marginal to modest efficacy advantage" over cheaper alternative therapies used to treat glioblastoma muliforme. (Id. ¶ 139.) Yet, Plaintiffs claim that Defendants exhorted their sales representatives to overstate the efficacy and safety of Temodar to doctors in order to inflate sales of the drug. (Id. ¶¶ 139, 141, 145, 147, 149.)

With respect to Plaintiffs' purported off-label promotion of the Intron Franchise Drugs, Plaintiffs allege that Schering marketed Intron A for the off-label treatment of superficial bladder cancer, renal cell carcinoma, chronic myelogenous leukemia, myeloma, metastatic melanoma and

Peyronie's disease. (Id. ¶ 150.) Further, they claim that Schering promoted the Intron Franchise Drugs to treat people with normal liver enzymes when the FDA had only approved these drugs to treat patients with elevated liver enzymes. (Id. ¶ 151.) Indeed, Plaintiffs point out that Intron A is not listed in the Compendia[4] to treat naive superficial bladder cancer patients and patients with metastatic melanoma or Peyronie's disease. (Id. ¶ 164.) Similarly, Intron A and Rebetol are not listed in the Compendia for the treatment of Hepatitis C patients with normal liver enzymes, but were marketed for these indications. (Id. ¶ 165.) Plaintiffs assert that, lacking evidence that the Intron Franchise Drugs were effective for some of the uses for which they were marketed, Defendants, nonetheless, promoted these drugs off-label as safe and effective for these conditions. (Id. ¶ 163.)

As part of a plan to increase the number of Intron Franchise and Temodar prescriptions written and drive up the price of the Subject Drugs, Defendants allegedly omitted or misrepresented information about the use and efficacy of these drugs. (Id. ¶¶ 126-28.) Defendants purportedly carried out their off-label promotion plan through a variety of methods, including, but not limited to:

a. using continuing medical education programs ("CME's") directed and controlled by Schering sales representatives to promote off-label uses of Temodar and Intron A; (Id. ¶ 118)

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[4] Under the Social Security Act, Medicare is required to cover all prescriptions for "any drugs or biologicals used in an anticancer chemotherapeutic regimen for a medically accepted indication." 42 U.S.C. § 1395x(t)(2)(A). The Act defines a "medically accepted indication" as an FDA-approved use, as well a use for which the drug has not been approved by the FDA but which is "supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service-Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information (or its successor publications), and other authoritative compendia as identified by the Secretary...." Id. § 1395x(t)(2)(B)

b. devising a program, dubbed the Consulting Care Network, where Schering-paid physicians would respond to queries by physicians by promoting Schering drugs for off-label use; (Id.)

c. marketing the Subject Drugs for off-label use at national and regional meetings of doctors and the health care industry; (Id.)

d. targeting doctors who prescribed competing drugs with a "barrage of off-label marketing techniques"; (Id. ¶ 119)

e. paying doctors who prescribed the Subject Drugs for off-label uses to speak at dinner lectures and other functions; (Id. ¶ 169)

f. entering into paid consulting agreements with physicians for which little or no work was required; (Id. ¶¶ 171-72) and

g. providing research and educational grants to Pharmacy Benefit Managers (PBMs) ostensibly to induce them to place the Subject Drugs on TPP formularies. (Id. ¶ 205.)

Plaintiffs contend that many of the details regarding the aforementioned marketing practices and the extent of Defendants' off-label promotion scheme have been purposely concealed by Defendants as to avoid criminal and civil liability. (Id. ¶¶ 260-68.) They conclude that the off-label marketing of the Subject Drugs contributed to a tenfold increase in the sales of Temodar and a doubling of sales for the Intron Franchise Drugs during the Class Period. (Id. ¶¶ 206, 208.)

Plaintiffs allege that Defendants effectuated their off-label marketing scheme through their own affirmative actions, and by conspiring with various third party marketing entities, namely ProEd Communications, Inc. ("ProEd"), OCC North America, Inc. ("OCC"), Bucom International ("Bucom") and Projects in Knowledge, Inc. ("PIK") (collectively the "Marketing Firms"). (Id. ¶ 210.) Specifically, Plaintiffs assert that Defendant Schering-Plough Corporation carried out the alleged off-label promotion through six separate and alternative enterprises: (1) Schering Sales (2) ProEd, (3) OCC, (4) Bucom, (5) PIK and (6) CTC. (Id. ¶ 280.) They claim

that the relationship between Schering and Schering Sales, a wholly owned subsidiary, constitutes an enterprise. (Id.) Moreover, Plaintiffs contend that Schering entered into "associations-in-fact" with the Marketing Firms and CTC, each of which constitutes a separate and distinct enterprise. (Id.) With respect to these "associations-in-fact," Plaintiffs claim that Schering designed and controlled each and every aspect of the Marketing Firms' activities with the singular goal of promoting the off-label use of the Subject Drugs. (Id. ¶¶ 210-24, 280.)

In addition to asserting claims against the Schering companies, Plaintiffs assert similar claims against Defendants Kogan, Heiden and Naughton based on their alleged "supervision and instigation" of the off-label marketing of the Subject Drugs. (Id. ¶¶ 93, 98, 216.) Plaintiffs contend that the off-label marketing scheme purportedly employed by Schering was conceived and implemented by Schering management, including Kogan and Heiden. (Complaint ¶¶ 228-232.) Moreover, Plaintiffs claim that the Individual Defendants took calculated and affirmative steps to conceal the off-label promotion practices from the FDA. (Id. ¶ 95.)

Plaintiffs argue that Defendants' off-label promotion of the Subject Drugs caused them ascertainable loss because the marketing schemes caused the TPPs "to place Temodar and Intron Franchise Drugs on their formularies, and ... cause[d] TPPs to pay for drugs in cases where they were not FDA-approved and/or effective." (Id. ¶¶ 112, 234-35, 249-54.) In addition, Plaintiffs were injured because Defendants' off-label marketing "caused doctors to write an increased number of prescriptions for certain Subject Drugs when they were off-label and/or not effective" and where there were less expensive alternative treatments on the market. (Id. ¶¶ 113, 236-46.) Moreover, the off-label promotion of the Subject Drugs allegedly caused ascertainable losses to the Plaintiffs by "inflating the price of the Subject Drugs and causing TPPs to pay more for

the[m] than they would have absent Schering's illegal sales and marketing scheme." (Id. ¶¶ 114, 247-48.) Plaintiffs claim that members of the proposed Class "paid billions of dollars that they otherwise would not have paid, absent Schering's illegal and fraudulent scheme." (Id. ¶ 233.)

On January 18, 2008, the Schering Defendants filed their motion to dismiss the Complaint pursuant to Fed. R. Civ. P. 9(b), 12(b)(1) and 12(b)(6). A short time later, on February 15, 2008, the Individual Defendants moved to dismiss the Complaint on similar grounds. Defendants assert that all of Plaintiffs' claims must be dismissed because Plaintiffs have failed to adequately plead that any one of the named Plaintiffs suffered a cognizable injury. With respect to the RICO and NJRICO claims, Defendants contend that these claims should be dismissed because (1) they are barred by the four year statute of limitations, (2) Plaintiffs have failed to allege predicate acts, (3) there is an insufficient causal nexus between the challenged conduct and the harm alleged, and (4) Plaintiffs have failed to make out the existence of a RICO enterprise. The Schering Defendants contend that Plaintiffs' state law claims must be dismissed for many of the reasons requiring dismissal of the RICO claims and further because these claims are preempted by federal law pursuant to Congress's grant of authority to the FDA to oversee pharmaceutical marketing.[5] The Schering Defendants also argue that, even if federal law does not preempt Plaintiffs' state law claims, Plaintiffs NJCFA claim must, nonetheless, be dismissed because the NJCFA does not apply to highly regulated activities such as pharmaceutical marketing. Moreover, they claim that the Court should dismiss Plaintiffs' NJCFA claim because

[5] In light of the Supreme Court's recent decision in Wyeth v. Levine, 129 S.Ct. 1187 (2009), in which the Court held that state law failure-to-warn claims asserted against a pharmaceutical manufacturer are not preempted by federal law, Defendants no longer contend that Plaintiffs' state law claims are preempted. (Letter from Plaintiffs' Counsel to the Court dated March 13, 2009; Docket Entry No. 192.)

the insurance companies, HMOs and TPPS are not entitled to sue under the statute.

STANDARD OF REVIEW

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1332(d) and has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367.

I. Motion to Dismiss Under Rule 12(b)(1)

Under Federal Rule of Civil Procedure 12(b)(1), a court must grant a motion to dismiss if it lacks subject-matter jurisdiction to hear a claim. "A motion to dismiss for want of standing is properly brought pursuant to Rule 12(b)(1), because standing is a jurisdictional matter." Ballentine v. U.S., 486 F.3d 806, 810 (3d Cir. 2007). Once a Rule 12(b)(1) challenge is raised, the plaintiff bears the burden of demonstrating the existence of subject matter jurisdiction. PBGC v. White, 998 F.2d 1192, 1196 (3d Cir. 1993). When considering a motion to dismiss for lack of jurisdiction pursuant to 12(b)(1), "no presumptive truthfulness attaches to plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." Mortensen v. First Federal Sav. & Loan Ass'n, 549 F.2d 884, 891 (3d Cir. 1977).

II. Motion to Dismiss Under Rule 12(b)(6)

In deciding a motion to dismiss pursuant to Rule 12(b)(6), courts must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008) (quoting Pinker v. Roche Holdings, Ltd., 292 F.3d 361, 374 n.7 (3d Cir. 2002)). A Rule 12(b)(6) motion to dismiss

should be granted only if the plaintiff is unable to articulate "enough facts to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). "The defendant bears the burden of showing that no claim has been presented." Hedges v. United States, 404 F.3d 744, 750 (3d Cir. 2005).

Plaintiffs' claims will be reviewed pursuant to "Federal Rule of Civil Procedure 8(a)(2)[, which] requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief[]' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" Twombly, 550 U.S. at 555 (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957)). However, "[w]hile a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." Twombly, 550 U.S. at 555 (internal citations omitted); see also FED. R. CIV. P. 8(a)(2). "Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Id. at 589 (internal citations omitted). "The pleader is required to 'set forth sufficient information to outline the elements of his claim or to permit inferences to be drawn that these elements exist.'" Kost v. Kozakewicz, 1 F.3d 176, 183 (3d Cir. 1993) (quoting 5A Charles Alan Wright & Arthur R. Miller, Federal Practice & Procedure Civil 2d § 1357 at 340 (2d ed. 1990)). And while a court will accept well-pled allegations as true for the purposes of the motion, it will not credit bald assertions or legal conclusions. Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 1997).

The Supreme Court has characterized dismissal with prejudice as a "harsh remedy." New

York v. Hill, 528 U.S. 110, 118 (2000). Dismissal of a count in a complaint with prejudice is appropriate if amendment would be inequitable or futile. Alston v. Parker, 363 F.3d 229, 235 (3d Cir. 2004). "When a plaintiff does not seek leave to amend a deficient complaint after a defendant moves to dismiss it, the court must inform the plaintiff that he has leave to amend within a set period of time, unless amendment would be inequitable or futile." Grayson v. Mayview State Hosp., 293 F.3d 103, 108 (3d Cir. 2002).

III. Pleading Requirements of Rule 9(b)

Plaintiffs assert RICO claims based on numerous allegations of wire fraud and mail fraud, which are subject to the heightened pleading standards of Fed. R. Civ. P. 9(b). Lum v. Bank of Am., 361 F.3d 217, 223-24 (3d Cir.2004). Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." "The purpose of Rule 9(b) is to provide notice of the 'precise misconduct' with which defendants are charged" in order to give them an opportunity to respond meaningfully to the complaint, "and to prevent false or unsubstantiated charges." Rolo v. City of Investing Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (citing Seville Indust. Machinery v. Southmost Machinery, 742 F.2d 786, 791 (3d Cir. 1984)).

To satisfy Rule 9(b), a plaintiff must "plead with particularity the 'circumstances' of the alleged fraud." Rolo, 155 F.3d at 658. Plaintiffs need not "plead the 'date, place or time' of the fraud, so long as they use an 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" Id. (citing Seville, 742 F.2d at 791). The Third Circuit has cautioned that courts should "apply the rule with some flexibility and should not

require plaintiffs to plead issues that may have been concealed by the defendants." Id. (citing Christidis v. First Pa. Mortg. Trust, 717 F.2d 96, 99 (3d Cir. 1983)).

ANALYSIS

Defendants' motion to dismiss seeks the dismissal of each of the nine (9) claims asserted in the Complaint. Defendants separately dispute the viability of each claim asserted by Plaintiffs and, as an initial matter, contest Plaintiffs' standing to bring their nine claims for relief.[6] The Court addresses each of these arguments in turn. (Schering Br. at 17-40.)

I. RICO and NJ RICO

Plaintiffs assert claims for violations of the relevant RICO and NJ RICO statutes (Counts I and II, respectively). Under 18 U.S.C. § 1964(c), "[a]ny person injured in his business or property by reason of a violation of [RICO's substantive provisions, 18 U.S.C. § 1962] may sue therefor in any appropriate United States district court and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee."[7] The Act further "makes it unlawful for 'any person' who is employed by or associated with 'any enterprise' affecting interstate commerce to 'participate, directly or indirectly, in the conduct of such enterprise's

[6] In order to have standing, a plaintiff must first demonstrate with particularity that he has suffered a concrete injury-in-fact. Interfaith Cmty. Org. v. Honeywell Int'l, 399 F.3d 248, 254 (3d Cir. 2005). To determine injury-in-fact, a court will "consider[] whether the alleged injury falls within the 'zone of interests' that the statute or constitutional provision at issue was designed to protect[.]" Anjelino v. New York Times Co., 200 F.3d 73, 88 (3d Cir. 1999). Because a court's injury-in-fact analysis is influenced by the statutory, constitutional or common law interests sought to be protected, the Court will consider whether Plaintiffs have adequately alleged injury-in-fact as part of its analysis of each of Plaintiffs' nine claims.

[7] The RICO statute's provision of a civil remedy was enacted to "turn [plaintiffs] into prosecutors, 'private attorneys general,' dedicated to eliminating racketeering activity...." Prudential Ins. Co. of America v. U.S. Gypsum Co., 359 F.3d 226, 236 (3d Cir. 2004) (quoting Rotella v. Wood, 359 U.S. 549, 550 (2000)).

affairs through a pattern of racketeering activity.'" Genty v. Resolution Trust Corp., 937 F.2d 899, 906 (3d Cir. 1991)(citing 18 U.S.C. §§ 1962(c), 1964(c)). To assert a valid claim under RICO, a plaintiff must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity, and an injury to property or business resulting from the offensive conduct. Sedima S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985)("Sedima"); Bonavita Elec. Contr., Inc. V. Boro Developers, Inc., 87 F. App'x 227, 231 (3d Cir. 2003). The statute defines racketeering by a list of criminal activities that constitute predicate acts for the purposes of RICO. Among the predicate acts listed are mail fraud and wire fraud, the acts which Plaintiffs have alleged in the case at bar. See 18 U.S.C. § 1961(a). In addition to the predicate acts of mail and wire fraud, Plaintiffs assert that the off-label promotion of the Subject Drugs by Schering and the Individual Defendants violated the New Jersey Commercial Bribery Statute, N.J.S.A. § 2C:41-10, the Travel Act, 18 U.S.C. § 1952, and the National Stolen Property Act, 18 U.S.C. § 2314. Plaintiffs also allege violations of the New Jersey RICO statute, N.J.S.A. 2C:41-4(c), based on the same predicate acts and pattern of racketeering activity as those alleged in support of their RICO claims. Because Plaintiffs' NJRICO claims parallel their federal RICO claims and are subject to the same standards of proof as those required by the federal statute, the Court addresses the RICO and NJRICO claims concurrently. See Cetel v. Commw. Life Ins. Co., 460 F.3d 494, 510 (3d Cir. 2006)(citing State v. Ball, 141 N.J. 142 (1995))("[T]he New Jersey Supreme Court believed the New Jersey RICO statute was and should be consistent with the federal RICO statute.").

Based on the Schering Defendants' submissions in support of their motion to dismiss, the Court considers whether Plaintiffs' RICO and NJRICO claims should be dismissed because: (1)

Plaintiffs have not adequately alleged injury, (2) the claims are barred by the applicable four-year statutes of limitations, (3) Plaintiffs have failed to allege a direct causal connection between the alleged RICO violations and the alleged injuries, (4) Plaintiffs have not adequately pled the requisite predicate acts of racketeering activity, and (5) none of the enterprises alleged in the Complaint are viable. (Schering Br. at 10-32.) Plaintiffs separately dispute each of the rationale offered by the Schering Defendants in support of their motion to dismiss. (Pl. Br. at 7-29.)

A. Injury

The Supreme Court has stated that a plaintiff "only has standing if, and can only recover to the extent that, he has been injured in his business or property by the conduct constituting the violation [of RICO]." Sedima, 473 U.S. at 496. While RICO injury is generally considered a question of Article III standing, 1964(c) of the RICO statute sets forth additional criterion that must be met. See DeMauro v. DeMauro, 115 F.3d 94, 96 (1st Cir. 1997)("There is plainly a case or controversy under Article III; but the statutory precondition of injury to business or property must also be met."). To establish RICO standing, "a RICO plaintiff [must] make two related but analytically distinct threshold showings ...:(1) that the plaintiff suffered an injury to business or property; and (2) that the plaintiff's injury was proximately caused by the defendant's violation of 18 U.S.C. § 1962." Maio v. Aetna, Inc., 221 F.3d 472, 483 (3d Cir. 2000).

Plaintiffs claim that they were injured in their business or property by reason of the Schering and Individual Defendants' violations of 18 U.S.C. § 1962(c). (Complaint ¶ 297.) They assert that "Defendants' wrongful activities harmed [TPP Plaintiffs] by causing them to place Temodar and Intron Franchise [D]rugs on their formularies, and then engaging in an illegal sales and marketing scheme to cause TPPs to pay for drugs in cases where they were not FDA-

approved and/or effective." (Complaint ¶ 112.) Specifically, Plaintiffs contend that they were injured because Schering's off-label marketing activities:

> (a) increas[ed] the number of off-label prescriptions of the Subject Drugs that patients and TPPs paid for; (b) caus[ed] patients and TPPs to pay for drugs that were not effective for the uses advertised; (c) caus[ed] patients and TPPs to pay for the Subject Drugs where there were cheaper alternative medications; (d) increas[ed] the purchase price of the subject drugs; and (e) caus[ed] TPPs, including Medicare supplemental insurers, to pay for non-covered drugs.

(Complaint ¶ 233.) Based on a review of the Complaint, the RICO Case Statement and Plaintiffs' submissions in opposition to the instant motions to dismiss, the Court divines four separate theories of RICO injury for which Plaintiffs seek to recover. As an initial matter, Plaintiffs suggest that they have suffered an economic loss based on Schering's off-label promotion of the Subject Drugs. Second, Plaintiffs claim that they were injured because they paid for prescriptions of the Subject Drugs where the drugs were ineffective for the uses for which they were prescribed. Third, Plaintiffs assert that they were injured where they paid for the Subject Drugs rather than cheaper alternative treatments. And fourth, Plaintiffs allege that they were injured by Defendants because they paid for a greater number of the Subject Drugs than they would have absent Defendants' off-label promotion plan and because the price of the Subject Drugs was artificially inflated by the plan. Defendants have moved to dismiss Plaintiffs' RICO and NJRICO claims, in part, based on Plaintiffs alleged failure to adequately allege injury. Defendants suggest that Plaintiffs' notions of RICO injury are inadequately pled and/or clearly impermissible at law. The Court will address each of Plaintiffs' four theories of injury in turn.

1. Off-Label Promotion

Plaintiffs assert that they have suffered cognizable injuries as a result of Schering's

promotion of the Subject Drugs for uses not approved by the FDA. The Court has noted that Defendant Schering Sales previously pled guilty to conspiracy to make false statements to the FDA concerning Schering's off-label marketing of Temodar and Intron A. As part of the plea agreement, Schering Sales "expressly and unequivocally admit[ted] that it knowingly, intentionally and willfully" conspired to make false statements to the FDA in order "to avoid scrutiny of its off-label marketing of Temodar and Intron A." Agreement Between Plaintiff United States and Defendant Schering Sales, August 24, 2006. Plaintiffs in this case contend that, "[a]s a result of Schering's illegal sales and marketing scheme, Named Plaintiffs and class members suffered an ascertainable loss by Defendants' [] increasing the number of off-label prescriptions of the Subject Drugs that patients and TPPs paid for[.]" (Complaint ¶ 233; see also Pl. Br. at 6 ("[Schering's] off-label marketing schemes directly harmed TPPs by wrongfully increasing the number of Subject Drugs that TPPs purchased where prescribed [] for off-label uses[.]").) Boiled down, Plaintiffs first theory of injury is essentially that the individual and TPP Plaintiffs have suffered an economic loss merely because Plaintiffs paid for Temodar and the Intron Franchise Drugs which Schering marketed for uses for which they had not been approved by the FDA.

Plaintiffs suggest that the off-label promotion of a pharmaceutical product in violation of the FDA regulations gives rise to actionable claims for relief by private plaintiffs. (See Transcript of October 9, 2008 Oral Argument at 10:22-11:5 ("Transcript").)[8] Plaintiffs are mistaken. At oral argument, Plaintiffs' counsel represented that Schering is liable to Defendants on all of

[8] It is clear that the Court may consider statements made by counsel at oral argument to clarify allegations made in the Complaint. See Maio, 221 F.3d at 485 n.12 (citing Alicke v. MCI Communications Corp., 111 F.3d 909, 911 (D.C. Cir. 1997)).

Defendants' claims, including the RICO and NJRICO allegations, by the mere fact that Schering promoted the Subject Drugs off-label. (See Transcript at 3:17-4:2.) According to Plaintiffs, no misrepresentations need be alleged. (Id. at 12:19-14:17.) Merely by promoting the Subject Drugs off-label in violation of the FDCA, Plaintiffs suggest that Schering has caused them economic loss by inducing them to purchase more of Temodar and Intron Franchise Drugs than they would have purchased but for the marketing activities. However, this theory of injury – injury based solely on the off-label promotion of the Subject Drugs – is patently illogical and plainly untenable. According to Plaintiffs, individual consumers who purchase a drug which has been marketed off-label have suffered injury even when a manufacturer truthfully represents the effectiveness of the drug and, remarkably, when the drug provides a more effective treatment than any available alternative. (Id. at 12:19-13:17.) Similarly, Plaintiffs contend that third party payors are injured by purchasing more Temodar and Intron Franchise Drugs than they would have absent off-label promotion, regardless of whether the Subject Drugs provide the most effective treatment for TPP beneficiaries. Plaintiffs suggest that, because third party payors budget their anticipated purchases of drugs based on approved uses, that TPPs are necessarily injured when a drug is marketed off-label. (Id. at 5:15-6:4.) Under this theory of injury, it matters not that individual consumers receive an effective drug that works as good as or better than expected. Nor is it of concern that the third party payors provide their beneficiaries with the most effective treatment available. Their only basis for alleging injury is that the purchased drugs were marketed off-label.

This first theory of injury is plainly an impermissible attempt by Plaintiffs to turn violations of the FDCA for off-label promotion into a private right of action under RICO and the

NJCFA. These Plaintiffs argue that no misrepresentations need be alleged to assert a RICO claim and, instead, that violations of the FDCA are alone sufficient to constitute the requisite underlying fraudulent act. But this theory of injury requires the Court to assume that off-label promotion is, by its very nature, fraudulent conduct. This is not reality. See In re Actimmune Mktg. Litig., -- F. Supp. 2d. ---, 2009 WL 1139585, at *18 n.6 (N.D. Cal. April 28, 2009)("[O]ff-label marking of an approved drug is itself not inherently fraudulent.")("Actimmune"); United States v. Caronia, 576 F.Supp.2d 385, 397 (E.D.N.Y. 2008)("Promotion of off-label uses is not inherently misleading simply because the use is off-label."). Instead, not all off-label promotion involves misrepresentations or dishonesty. Rather, the off-label use of pharmaceutical products is both prevalent and is, often times, the best means for providing effective treatment for patients. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 351 n.5 (2001)(recognizing that off-label use "often is essential to giving patients optimal medical care")(internal citations and quotations omitted). Additionally, Plaintiffs' theory of injury based on the off-label promotion of the Subject Drugs would require the Court to ignore the many well-reasoned decisions in which courts have held that purchasers of pharmaceutical products have no private cause of action where they receive the benefit of their bargain in the form of effective drugs. See Williams v. The Purdue Pharma Co., 297 F.Supp.2d 171, 176 (D.D.C. 2003)("Without alleging that a product failed to perform as advertised, a Plaintiff has received the benefit of his bargain and has no basis to recover purchase costs."); Rivera v. Wyeth-Ayerst Laboratories, 283 F.3d 315, 320 (5th Cir. 2002)(finding that plaintiff had not suffered economic injury where she received the safe and effective painkiller she bargained for.); Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 380 (D.N.J. 2004)(summary judgment entered in favor of defendants on plaintiffs' consumer fraud and

common law claims relating to plaintiffs' purchases of Vioxx where plaintiffs "got the effective arthritis remedy they bargained for."). The Court is not willing to accept that a plaintiff could somehow be injured by purchasing a drug that is as effective, or more effective, than alternative treatments simply because the drug was marketed off-label.

The Court is reminded that the Complaint was filed on the heels of FDA regulatory actions and government investigations which resulted in serious criminal and civil penalties being assessed against the Defendants. There is no question that the illegal conduct to which Schering Sales pled guilty represents this corporate Defendant's reprehensible disregard for the vital role the FDA plays in ensuring the safety of consumer pharmaceutical products. Yet, as condemnable as Schering's flouting of FDA regulations may be, the off-label promotion of a pharmaceutical product in violation of the FDCA simply does not give rise to fraud-based rights of action under RICO. See In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F.Supp.2d 1282, 1290 (C.D. Cal. 2008)("But the FDCA provides no private right of action for violations thereof, and what the FDCA does not create directly, RICO cannot create indirectly." (citing Sandoz Pharms. v. Richardson-Vicks, Inc., 902 F.2d 222, 231 (3d Cir. 1990))). The Court will not permit Plaintiffs to shoehorn allegations of off-label promotion within the rubric of RICO without pleading the essential RICO elements of injury and causation. Instead, Plaintiffs' allegations should be reviewed by the FDA for violations of the FDCA and accompanying regulations.

Because neither the individual plaintiffs nor the TPPs suffer cognizable injury when they pay for drugs which are marketed off-label, Plaintiffs' claims premised on this theory of injury will be dismissed.

2. Effectiveness of the Subject Drugs

Plaintiffs' second theory of RICO injury is that "[Schering's] scheme caused [them] to pay for Subject Drugs where they were ineffective." (Pl. Opp. Br. at 8.) Defendants move to dismiss the RICO and NJ RICO claims because they claim that Plaintiffs have not actually contested the safety or effectiveness of Temodar or the Intron Franchise Drugs. (Schering Br. at 11.) Instead, they have merely alleged that the Subject Drugs were not approved by the FDA as effective for the treatment for certain indications. And to the extent that the Court finds that Plaintiffs have contested the effectiveness of the Subject Drugs for a small number of off-label indications, the Defendants nonetheless conclude that Plaintiffs claims should be dismissed because "[Plaintiffs] never allege that these allegations are relevant to them." (Id. at 13.) In particular, Defendants submit that "the named consumer [P]laintiffs do not at all contest the safety or effectiveness of the particular drugs for which they paid, or even allege that they were prescribed drugs off-label[,]" and that "the TPPs do not even identify any of their beneficiaries who took the Subject Drugs for any off-label use or allege the circumstances or results of such treatment -- information presumably within [P]laintiffs' control, for which they certainly do not require discovery." (Id.) Plaintiffs respond by citing In re Neurontin Mktg. and Sales Practices Litig., 433 F. Supp. 2d 172 (D. Mass. 2006), a case in which Judge Saris found that class plaintiffs had alleged injury sufficient to permit their RICO claims to survive defendants' motion to dismiss where they "alleged that Neurontin was ineffective, and, as such, paid for a drug that didn't work as promised." Id. at 185. In the instant litigation, Plaintiffs claim they have suffered cognizable injury because, "[e]ven if the Subject Drugs were effective for some uses,

[Schering's] scheme caused Plaintiffs to pay for Subject Drugs where they were ineffective." (Pl. Br. at 8.)

Plaintiffs suggest that the mere act of pleading any injury to business or property resulting from an alleged RICO violation is sufficient to withstand a motion to dismiss. (Pl. Br. at 26.) While the Supreme Court has stated that the RICO statute is to be read broadly, the Third Circuit has held, based on the language of § 1964(c), that not every plaintiff has a federal cause of action arising under RICO. See Maio, 221 F.3d at 483 (internal citations and quotations omitted). Contrary to Plaintiffs' suggestion, simply alleging an injury to business or property resulting from an alleged RICO violation is not enough to defeat a motion to dismiss. Such a rule would create a strange state of affairs in which a complaint could withstand a motion to dismiss simply through a plaintiff's formulaic recitation of the statutory RICO elements. But see Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009)("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). Instead, a RICO claim must include an adequately pled injury, which "requires proof of a concrete financial loss and not mere injury to a valuable intangible property interest." Maio, 221 F.3d at 483. (internal citations and quotations omitted). In short, a plaintiff must do more than plead any theory of injury – the theory of injury must be one that is cognizable under RICO. See, e.g., McLaughlin v. American Tobacco Co., 522 F.3d 215, 228-29 (2d Cir. 2008)("McLaughlin"); Maio, 221 F.3d at 483; District 1199P Health and Welfare Plan v. Janssen, L.P., 2008 WL 5413105, at *8 (D.N.J. Dec. 23, 2008)("Janssen").

In the context of alleged fraudulent marketing of a pharmaceutical product, both Plaintiffs and Schering cite cases in which courts have held that injury is adequately pled only

where a plaintiff alleges that a purchased drug was either unsafe, ineffective or somehow worth less than the price paid for the drug. (Pl. Br. at 7-8 (citing Neurontin, 433 F. Supp. 2d at 185-86); Schering Br. at 11-12 (citing Williams, 297 F. Supp. 2d 171 (D.D.C. 2003).) The weight of authority in this area supports this theory of injury. See Rivera, 283 F.3d at 320; Janssen, 2008 WL 5413105, at *7-8; Prohias v. Pfizer, Inc., 485 F. Supp. 2d 1329, 1335 (S.D. Fla. 2007); Heindel, 381 F. Supp. 2d at 380; see also Maio, 221 F.3d at 494 (RICO plaintiffs did not plead a sufficient theory of injury where they failed to allege "that the level of care they received under [an HMO plan] actually was inferior to that which was promised, and therefore 'worth less' than they paid for it."). Plaintiffs suggest that they have adequately alleged that they have been injured because the Subject Drugs for which they paid were ineffective. (Pl. Br. at 8.) In contrast, Defendants assert that Plaintiffs have not adequately pled injury because Plaintiffs have merely alleged that the Subject Drugs were "not FDA-approved and/or ineffective[,]" a characterization that is decidedly different from allegations that the drugs were unsafe or ineffective. (Schering Br. at 12-13.) Defendants note that a lack of FDA approval for certain indications is, by no means, a determination that the Subject Drugs are either unsafe or ineffective. (Id.) Rather, they suggest that off-label use of prescription drugs is prevalent in the practice of medicine and sometimes provides the most effective course of treatment. (Id.) Defendants posit, therefore, that Plaintiffs have not suffered a cognizable injury because the mere allegation that Plaintiffs paid for the Subject Drugs for the treatment of conditions not approved by the FDA "does not mean that Plaintiffs failed to receive an effective treatment or other value." (Id. at 13.)

Despite Plaintiffs contention that they "specifically alleged that the Subject Drugs were

not effective at all for many of the promoted uses and that Schering knew that," the Court finds very little with their pleadings to substantiate this assertion. (Letter from Plaintiffs' Counsel, January 8, 2009, Docket Entry No. 187, at 2.) The Court has thoroughly reviewed the Complaint and the RICO Case Statement and is persuaded that Plaintiffs have failed to plead that the Subject Drugs were ineffective. Plaintiffs repeatedly mention the effectiveness of the Subject Drugs, alleging that the drugs were "not FDA-approved and/or effective" or were "off-label and/or not effective." (See Complaint ¶¶ 112, 113.) Plaintiffs also purport to dispute the effectiveness of the Subject Drugs with allegations such as:

- "[Schering] *did not have clinical data* to back up [its] claims[;]" (Complaint ¶ 125) (emphasis added)
- "Schering's own internal documents show that it believed *there was little evidence* that Temodar worked better than cheaper alternative drugs...[;]" (Complaint ¶ 128) (emphasis added)
- "Temodar demonstrated '*limited efficacy*' ... [and] had only a *'marginal to modest efficacy advantage*' over cheap alternative therapies...[;]" (Complaint ¶¶ 137, 139) (emphasis added)
- "...Schering *did not have evidence* to support its claims that Intron Franchise Drugs were effective for some of their off-label uses[;]" (Complaint ¶ 163) (emphasis added)
- Schering's off-label marketing plan "caus[ed] doctors to prescribe Temodar and Intron Franchise Drugs at an increased frequency *for uses not approved as safe and effective* by the FDA[.]" (Complaint ¶ 234) (emphasis added)

Recurrent among these and other allegations contained in the Complaint are Plaintiffs' citations to Schering's lack of evidence to support claims made regarding the efficacy of the Subject Drugs or to the lack of FDA approval for the treatment of certain indications.

Plaintiffs' allegations of insufficient evidence and lack of FDA approval are not adequate to plead RICO injury because they fail to assert that the Subject Drugs were ineffective, unsafe, or somehow worth less than what Plaintiffs paid for the drugs. Instead, Plaintiffs have merely alleged that the Subject Drugs were not FDA approved for certain conditions or that the relative effectiveness of the Subject Drugs had not been proven through conclusive evidence. As the Court has already held, there is a clear and decisive difference between allegations that actually contest the safety or effectiveness of the Subject Drugs and claims that merely recite violations of the FDCA, for which there is no private right of action. See Actimmune, 2009 WL 1139585, at *12 ("[M]any of the plaintiffs' allegations conflate a false and misleading statement under the FDCA, i.e., one that occurs when the drug label does not match the promoted assertion about the drug, and a false and misleading statement *about the drug itself* that can give rise to a claim under RICO.")(italics in original). By way of a hypothetical, consider a case in which a pharmaceutical manufacturer markets snake oil pills, labeled as "Drug X," for certain conditions when the manufacturer knows it is merely hocking snake oil. Under this example, a purchaser of Drug X could plead RICO injury because the pills are have no efficacy whatsoever for the uses for which they are marketed. In contrast, the prospective Plaintiffs in case at bar allege that Schering marketed Temodar and the Intron Franchise Drugs off-label for indications for which Schering had at least some data to support the claims that the Subject Drugs were safe and as effective or more effective than available alternative therapies. Marketing of this sort is

commonly referred to as "puffery," not fraud. While puffery may be actionable under the FDCA, it is not a violation of RICO. See Actimmune, 2009 WL 1139585, at *16 (discussing defendants' efforts to market a drug in the "best light possible[,]" the court observed that "[t]here is a clear distinction in the law between puffery and fraud."); Maio v. Aetna, Inc., 1999 WL 800315, at *2 (E.D.P.A. Sept. 29, 1999), aff'd, 221 F.3d 472 (3d Cir. 2000) (generalized claims regarding an HMO plan's quality of care "are puffery, and do not constitute a fraudulent inducement....").

Tellingly, even Neurontin, the case relied upon in large measure by Plaintiffs, supports the Court's conclusion that Plaintiffs have failed to adequately plead RICO injury. Plaintiffs' allegations closely mirror those made in Neurontin, where the coordinated plaintiffs alleged that Neurontin "was not proven to be safe and efficacious, effective and useful[,]" was "not proven to be safe," and where "[n]o clinical trial showed that Neurontin was safe or effective for [certain] conditions[.]" In re Neurontin Mktg. and Sales Practices Litig., No. 04-10981, slip op. at 22 (D. Mass. Jan. 31, 2006)(Report and Recommendation of Mag. Sorokin). Magistrate Judge Sorokin's Report and Recommendation, which was adopted in large part by Judge Saras, recommended dismissing coordinated plaintiffs' RICO claims because the coordinated plaintiffs had failed to adequately plead a cognizable RICO injury. Id. Judge Sorokin concluded that "[i]t is simply not enough to claim that Neurontin had not been proven to be effective; rather, [p]laintiffs must allege that it was ineffective." Id. (explicitly adopted by Judge Saras in Neurontin, 433 F. Supp. 2d at 185). Similarly, in a recent opinion by this Court dismissing RICO claims by plaintiff third party payors seeking economic damages sustained as a the result of alleged off-label promotion of Risperdal, Judge Wolfson concluded that RICO injury based on

overpayment for pharmaceuticals requires "allegations that Defendants' drug was on some level 'inferior and therefore worth less than what [Plaintiffs] paid for it.'" Janssen, 2008 WL 5413105, at *8 (quoting Maio, 221 F.3d at 488). Because the Plaintiffs have not actually pled that the Subject Drugs were ineffective, the cannot pursue RICO claims under this theory of injury.

Furthermore, even if the Court accepts that Plaintiffs have pled a cognizable theory of RICO injury, which it does not, Plaintiffs' RICO claims must still be dismissed because Plaintiffs fail to plead a factually-supported injury that was caused by the conduct challenged in the Complaint. For starters, in the few instances where Plaintiffs do allege that they paid for ineffective drugs, they do so summarily. (See Complaint ¶ 233: Schering's conduct "caus[ed] patients and TPPs to pay for drugs that were not effective for uses advertised."; ¶ 236: Schering's conduct "caused doctors to prescribe Temodar and Intron Franchise [Drugs] in instances where they were not effective."; ¶ 241: "Plaintiffs...pa[id] for an increased amount of medication where it did not provide a benefit to patients.") Clearly the Court must accept as true all factually supported allegations in the Complaint on a motion to dismiss under Rule 12(b)(6), but just as clear is the fact that the Court " need not accept as true 'unsupported conclusions and unwarranted inferences.'" City of Pittsburgh v. West Penn Power Co., 147 F.3d 256, 263 n. 13 (3d Cir. 1998) (quoting Schuylkill Energy Resources, Inc. v. Pennsylvania Power & Light Co., 113 F.3d 405, 417 (3d Cir. 1997)). "[C]ourts have an obligation in matters before them to view the complaint as a whole and to base rulings not upon the presence of mere words but, rather, upon the presence of a factual situation which is or is not justiciable." Id. at 263. Even under the most liberal construction, the factual assertions contained in the Complaint do not support Plaintiffs' allegation that the Subject Drugs were ineffective. Eschewing facts, Plaintiffs do not

identify or otherwise describe with specificity any instances in which a named plaintiff actually purchased, paid for or consumed an ineffective drug. This sort of pleading was expressly rejected in Neurontin, where, as part of a their state consumer protection claims, coordinated plaintiffs they alleged that Neurontin was ineffective. 433 F. Supp. 2d at 185. Judge Saris, however, considered the complaint in its entirety and concluded that coordinated plaintiffs could not allege RICO injury based on a single conclusory allegation of ineffectiveness. Id. In so concluding, she distinguished between the pleadings made by the class plaintiffs, who explicitly pled that Neurontin was ineffective, and the claims asserted by the coordinated plaintiffs, who merely made a single conclusory allegation that the drug was ineffective. Id. Unlike the class plaintiffs in Neurontin, Plaintiffs here never allege that they, themselves, paid for the Subject Drugs for indications for which it was ineffective. See Neurontin, No. 04-10981, slip op. at 21 ("[class] [p]laintiffs claim that they received no greater relief from, or treatment of, their medical conditions than they would have received from a placebo."). Similar to the Neurontin coordinated plaintiffs, these Plaintiffs merely assert that Temodar and the Intron Franchise Drugs were not proven effective for some conditions and indications, but fail to identify one individual Plaintiff who received a prescription and paid for the Subject Drugs to treat a condition for which the Subject Drugs were ineffective. Likewise, Plaintiffs do not allege that a single TPP ever paid for the Subject Drugs or reimbursed a beneficiary for the cost of the Subject Drugs to treat an indication for which the drugs ineffective. In light of the dearth of factual heft supporting Plaintiffs' theory of injury, the Court simply will not accept Plaintiffs' conclusory allegations as proof that the Subject Drugs were ineffective.

In a class action, "named plaintiffs who represent a class must allege and show that they

personally have been injured, not that injury has been suffered by other, unidentified members of the class...." Lewis v. Casey, 518 U.S.343, 347 (1996) (quotations omitted). Third Circuit precedent is clear that a plaintiff seeking to assert a RICO claim based on mail or wire fraud "must allege what happened to them." Rolo, 155 F.3d at 659. As the Court has stated, Plaintiffs have not alleged that any named plaintiff purchased one or more of the Subject Drugs that was prescribed and used for a condition for which it was ineffective. Moreover, TPP plaintiffs do not identify even a single beneficiary who took Temodar or the Intron Franchise Drugs for an off-label use and they fail to describe circumstances under which any named plaintiffs received no benefit from the Subject Drugs. Plaintiffs presumably recognize the paltriness of their pleadings, so they contend that "some TPPs lack information sufficient to identify precisely which of their beneficiaries took the Subject Drugs for off-label or ineffective uses[]" because "the necessary data is in [Schering's], or a third party's, possession." (Pl. Br. at 7.) The Third Circuit has cautioned that courts should apply Rule 9(b)'s specificity of pleadings requirement for claims based on fraud "with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants[.]" Rolo, 155 F.3d at 658. Yet, facts that would lend support to Plaintiffs' theory of injury in this case, such as the identities of beneficiaries on whose behalf the TPPs have paid for the Subject Drugs or the number of Temodar and Intron Franchise prescriptions for which they have paid, are not the sort of facts that are within the control of, and therefore the subject of concealment by, the Defendants. Instead, the identities of beneficiaries on whose behalf the TPPs have purchased the Subject Drugs, the amount of money paid for the Drugs and whether the Drugs were prescribed off-label are facts that are presumably within the control of Plaintiffs or third parties. Nevertheless, these important details are nowhere to be

found within the Complaint or RICO Case Statement and Plaintiffs have not described any efforts to uncover them. See Kirtley v. Wadekar, 2006 WL 2482939, at *3 (D.N.J. Aug. 25, 2006) (dismissing consumer fraud claims against pharmaceutical manufacturer where "[p]laintiffs do not allege with particularity any of the facts that would be expected to be within their knowledge: exactly who bought exactly what product when, relying on what false representations made when by whom."). Moreover, even where factual information may be within the domain or control of a defendant, such as the identities of the doctors who received promotional information, a plaintiff must still "accompany their legal theory with factual allegations that make their theoretically viable claim possible." In re Burlington Coat Factory Secs. Litig., 114 F.3d 1410, 1418 (3d Cir. 1998). Yet, Plaintiffs nowhere allege facts to support the theory that the named TPPs actually paid for one or more of the Subject Drugs to treat an off-label indication for which the drug was ineffective.

In determining whether a plaintiff has adequately pled injury, a court must evaluate the allegations contained in the complaint respecting the named plaintiffs. See Rolo, 155 F.3d at 659. "In the absence of pleadings that sufficiently establish the relation between the injury asserted and the injurious conduct alleged for at least one of the plaintiffs, there can be no cognizable claim under RICO." Actimmune, 2009 WL 1139585, at *13. Plaintiffs pleadings are plainly insufficient to support a finding that consumers and TPPs suffered an injury by paying for ineffective drugs. The Complaint simply does not allege that the Subject Drugs were ineffective, never mind that the drugs were ineffective for off-label uses for which they were purchased by one or more of the named Plaintiffs. Here, the Court would have to suspend disbelief to conclude that the Complaint sets forth facts sufficient to find that the named individual and third

party payor plaintiffs suffered an injury to their business or property as a result of the alleged off-label marketing of the Subject Drugs.

Plaintiffs pleadings do not support their assertion that they have pled that the Subject Drugs were unsafe or ineffective. Instead, as the Court has noted, Plaintiffs' allegations amount to no more than claims that Schering marketed the Subject Drugs off-label and in certain instances where they may not have had conclusive data regarding the efficacy of the drugs. Because Plaintiffs are not injured when they receive the benefit of their bargain in form of the Subject Drugs, they have failed to allege a cognizable theory of injury. Therefore, to the extent that Plaintiffs allege that they were suffered an injury or ascertainable loss by paying for unsafe or ineffective drugs, Plaintiffs claims will be dismissed.

3. Alternatives to the Subject Drugs

Plaintiffs also suggest that they were injured when Schering's off-label promotional activities "caus[ed] patients and TPPs to pay for Subject Drugs where there were cheaper alternative medications[.]" (Complaint ¶ 233.) Plaintiffs allege economic loss based on the supposition that they would have purchased cheaper and equally effective alternative treatments but for Schering's off-label promotion of Temodar and the Intron Franchise Drugs. (Id. ¶¶ 242-46.) According to Plaintiffs, they have adequately pled a concrete financial loss under this theory because they specifically allege that Defendants (1) marketed Temodar off-label for GBM where "there was little evidence that Temodar worked better than cheaper alternative drugs" and (2) marketed Temodar off-label for metastatic melanoma when there was "[m]arginal if any efficacy advantage" over DTIC, a generic treatment. (Id. ¶¶ 128, 144.) They assert that their resulting economic loss is equal to the "price differential between the cost of the Subject Drugs and

cheaper available alternatives[.]" (Id. ¶ 115.) Defendants contend that Plaintiffs' RICO claims must be dismissed under this alternate theory of RICO injury because Plaintiffs received precisely what they bargained for when they purchased the Subject Drugs -- drugs that were effective to treat the indications for which they were used. (Schering Br. at 14.) Defendants additionally argue that "the Complaint fails to allege concrete facts demonstrating that the existence of alternative treatments injured these [P]laintiffs in particular" and "fails to identify any circumstances in which Schering's alleged conduct induced a physician to prescribe one of the [S]ubject [D]rugs instead of an alleged alternative." (Id. at 15-16.) Absent specific allegations that the Subject Drugs were ineffective or unsafe as used by the Plaintiffs or that cheaper treatments were available to these Plaintiffs, but were not prescribed because of the conduct of the Schering Defendants, the Schering Defendants conclude that Plaintiffs' claims must be dismissed in their entirety. (Id.)

Plaintiffs claim their theory of injury compares favorably with the theory of which the Second Circuit approved in Desiano v. Warner-Lambert Co., 326 F.3d 339, 351 (2d Cir. 2003) ("Desiano"), where the Court found that TPP plaintiffs could sue under the NJCFA based on allegations that plaintiffs purchased a drug, Rezulin, rather than lower-priced alternatives where the drug manufacturer allegedly misrepresented the drug's safety. In Desiano, plaintiff health benefit providers and third party payors sued Warner-Lambert alleging that the manufacturer marketed Rezulin as safe and effective for the prevention of diabetes when, in actuality, the drug maker knew that the drug caused serious adverse side effects. Id. at 344-45. The district court found that Rezulin actually benefitted many consumers who purchased the drug and, therefore, dismissed the claims under Rule 12(b)(6) for failure to allege a direct and cognizable injury. In

re Rezulin Prods. Liab. Litig., 171 F.Supp.2d 299, 301 (S.D.N.Y. 2001). The Second Circuit reversed, holding that the TPPs sufficiently alleged direct harm in the form of payment for purchases of Rezulin that they would not have made had they not been misled by Warner-Lambert's misrepresentations regarding Rezulin's safety. Desiano, 326 F.3d at 349. In reversing the district court, the Court implicitly adopted the plaintiffs' argument that the injuries asserted by TPPs which paid for Rezulin are not derivative of injuries to beneficiaries because the TPPs allege that they, themselves, were deceived by misrepresentations made in marketing the drug. Id. Therefore, the Court noted that even if beneficiaries receive a drug that works as safely and effectively as alternatives, "[TPPs] would be able to claim ... that defendants engaged in a scheme to defraud [them], and that the compan[ies] suffered direct economic losses as a result[]" of purchasing Rezulin rather than lower-cost alternatives. Id. at 350. Plaintiffs further direct the Court's attention to In re Bextra and Celebrex Mktg., Sales Practices and Prod. Liab. Litig., 2007 WL 2028408 (N.D. Cal. July 10, 2007)(consumer fraud claims) and In re Zyprexa Prod. Liab. Litig., 493 F. Supp. 2d 571 (E.D.N.Y. 2007)(RICO claims), two cases in which courts have relied upon Desiano in holding that purchasers of drugs that were allegedly marketed fraudulently had sufficiently alleged injury by claiming that they would have purchased cheaper, equally effective alternative treatments but for the misrepresentations made by the manufacturers. Therefore, the instant Plaintiffs conclude that they have adequately alleged injury by alleging that they would have purchased cheaper alternative treatments absent the alleged misrepresentations regarding the efficacy of Temodar and the Intron Franchise Drugs.

Plaintiffs' reliance on Desiano and its progeny for the notion that they have adequately alleged injury by claiming that they would have purchased cheaper alternative treatments but for

Schering's alleged misrepresentations is misplaced. As a primary matter, the vitality of Desiano is questionable in light of the Second Circuit's recent decision in McLaughlin v. American Tobacco., 522 F.3d 215 (2d Cir. 2008). In McLaughlin, plaintiffs alleged that they relied upon defendants' misrepresentations regarding the health effects of light cigarettes and, therefore, suffered RICO injury to the extent that they paid more for light cigarettes than they would have had they known the truth about the relative health benefits of lights versus full-flavored cigarettes. The Second Circuit rejected plaintiffs' theory of RICO injury, holding that the proposed theory would impermissibly allow for expectation-based damages when RICO compensates only for injury to "business or property."[9] Id. at 228. The Court posited that the tobacco company's "misrepresentation could in no way have reduced the value of the cigarettes that plaintiffs actually purchased[.] [Instead,] they simply could have induced plaintiffs to buy [l]ights instead of full-flavored cigarettes." Id. at 229. Since the value of the product that was actually purchased was not diminished by plaintiffs' misrepresentations, the Court concluded that plaintiffs theory of injury was not cognizable under RICO. Id. at 228-29; see Janssen, 2008 WL 5413105, at *6 (discussing McLaughlin). In this case, there is no allegation that the relative values of the Subject Drugs were diminished by Schering's alleged marketing. Instead, Plaintiffs admit that Temodar and the Intron Franchise Drugs were as effective and sometimes more effective than available alternatives for treating many off-label conditions.

Plaintiffs reliance on Desiano and its offspring is misguided because the facts pled in that

[9] In McLaughlin, the Second Circuit did not go so far as to bar plaintiffs from ever asserting RICO claims for injury to expectancy interests, but it foreclosed RICO plaintiffs from claiming injury to expectancy interests in cases like the instant action which sound in fraud in the inducement. Id. at 228-29.

case are clearly distinguishable from those pled here. In Desiano, plaintiffs alleged that they were injured because they, themselves, were deceived by the manufacturer's alleged misrepresentations. 326 F.3d at 349 n.9. However, Plaintiffs in the case at bar do not contend that they were deceived by Schering's alleged misrepresentations. Rather, Plaintiffs assert that Schering's misrepresentations were directed at physicians who were, in turn, influenced to prescribe the Subject Drugs for off-label uses, thereby injuring the Plaintiffs as purchasers of the drugs.[10] This distinction is an important one. Indeed, the Second Circuit explicitly noted in Desiano that it was reversing the district court's dismissal of the complaint because the plaintiff insurers alleged that they, and not third parties, had been misled:

> Plaintiffs allege an injury directly to themselves[.]... Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, and that this fraud directly caused economic loss to them as purchasers, *since they would not have bought Defendants' product, rather than available cheaper alternatives, had they not been misled by Defendants' misrepresentations.* Thus the damages – the excess money Plaintiffs paid Defendants for the Rezulin that they claim they would not have purchased 'but for' Defendants' fraud – were in no way 'derivative of damage to a third party.'

326 F.3d at 349 (footnote omitted)(emphasis added). The Second Circuit drew an clear distinction between plaintiffs who allege direct injury resulting from misrepresentations aimed at them and those who assert injury based on misrepresentations aimed at third parties.[11] For this

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[10] Likewise, the court in Zyprexa concluded that plaintiffs had adequately pled that Eli Lilly promoted Zyprexa as safer and more effective than alternatives when, in fact, the manufacturer knew this to be untrue. Zyprexa, 493 F.Supp.2d at 577-78.

[11] The court in Bextra discounted the distinction between misrepresentations aimed at plaintiffs and those directed at prescribing physicians in determining that plaintiffs had adequately pled injury in fact. 2007 WL 2028408, at *6. Yet, in In re Rezulin, 525 F.Supp.2d 436 (S.D.N.Y. 2007), the court held that Desiano "has no bearing" in a case where, as here, "plaintiffs allege that they were injured because patients and the medical community were misled." Id. at 442. Notwithstanding Bextra, the Rezulin court's reading of Desiano's clear

reason, Desiano is very different from the instant case in which Plaintiffs allege that the Schering Defendants' misrepresentations were directed at third parties and not Plaintiffs.

Notably, Plaintiffs completely ignore the Third Circuit's decision in Maio v. Aetna, Inc., 221 F.3d 472 (3d Cir. 2000), a case which is binding on this Court and is directly on point. In Maio, purchasers of health insurance brought RICO claims alleging that they overpaid for health benefits based on misrepresentations made by Aetna health maintenance organizations (HMOs). Plaintiffs alleged that they suffered an injury to property in the form of "financial loss stemming from their overpayment for their membership in Aetna's HMO plan." Id. at 485. They sought to recover the difference in value between the health insurance promised and the health insurance actually received. The Third Circuit affirmed the district court's dismissal of plaintiffs' RICO claims, holding that plaintiffs' theory of injury for "concrete financial loss" was not cognizable under RICO because plaintiffs failed to allege that they "were denied medically necessary benefits, received inadequate, inferior or delayed medical treatment, or even worse, suffered personal injuries as a result [of Aetna's conduct.] Id. at 488. While not explicitly articulated as such, Plaintiffs in this case allege essentially the same theory of RICO injury as that rejected by the Third Circuit in Maio. In Maio, the plaintiffs alleged that they were injured because, as a result of Aetna's misrepresentations, they paid more for health insurance than the benefits were otherwise worth. Similarly, Plaintiffs here allege that, as a result of Schering's misrepresentations, they paid more for the Subject Drugs than other equally effective drugs. Stated another way, both sets of plaintiffs suggested that they suffered concrete financial losses because they paid more for the health care "product" they received than what they would have

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language is more sensible.

paid but for Aetna's and Schering's alleged misrepresentations. And just as plaintiffs pleadings in Maio failed to allege cognizable injury to business or property, Plaintiffs in this action have failed to adequately plead that any individual consumers or TPP beneficiaries "received inadequate[or] inferior [drugs] or even worse, suffered personal injuries as a result of" Defendants' alleged misrepresentations."[12] Id. at 488.

In determining that Plaintiffs have not sufficiently alleged RICO injury, the Court is further guided by the thoughtful analysis contained in Judge Wolfson's recent decision in Janssen. In that case, TPP plaintiffs pled RICO injury for overpayment for the drug Risperdal, a second generation antipsychotic medication. Plaintiffs asserted that defendants' misrepresentations regarding Risperdal's safety and efficacy caused concrete financial loss in the form of purchases of Risperdal rather than cheaper, equally effective alternative antipsychotic drugs. The plaintiffs alleged that, in truth, Risperdal was "neither more effective nor safer than older typical antipsychotics[,]" and "none of the second generation antipsychotics[, including Risperdal,] are superior in efficacy to the cheaper[,] older typical antipsychotics." Janssen, 2008 WL 5413105, at *7 (quoting Complaint ¶ 51). Therefore, "[p]laintiffs allege[d] that they were fraudulently denied comparably safe and effective, cheaper alternatives to Risperdal and overpaid hundreds of millions of dollars for doses of Risperdal that were prescribed by physicians because of Defendants' off-label marketing scheme." Id. at *3 (citations omitted). In a well-reasoned opinion, Judge Wolfson dismissed plaintiffs' RICO claims, finding that plaintiffs "fail[ed] to sufficiently allege a cognizable RICO injury under federal or New Jersey law[.]" Id. at *8. Relying upon Maio, Judge Wolfson concluded that "[p]laintiffs' allegations that there are more

[12] See discussion of "Effectiveness of the Subject Drugs," supra., at 20-31.

'cost-effective' alternatives do not meet the required pleading of overpayment as a concrete financial loss." Id. (citation omitted). Rather, in order to plead RICO injury, the court held that plaintiffs would have to allege "that the drug was inferior on some level and worth less than what they paid for it."[13] Id. The Plaintiffs in this action do not make such an allegation. Instead, they merely assert that cheaper alternatives to the Subject Drugs were available during the proposed class period.

Even if the Court were to accept that, in spite of Maio and Janssen, RICO injury can be pled by alleging the existence of cheaper, equally effective alternative drugs, Plaintiffs' pleadings in this case are still inadequate because Plaintiffs have not alleged that the existence of cheaper alternative treatments injured the named Plaintiffs in particular. Rolo, 155 F.3d at 659 ("[P]laintiffs must allege what happened to them."). In Rolo, the Third Circuit concluded that purchasers of real estate did not sufficiently plead injury under RICO where the plaintiffs described the alleged fraudulent real estate marketing scheme in great detail, but failed to make specific allegations about how the scheme personally injured them. 155 F.3d at 658-59. Here, only one of the individual Plaintiffs, Angela Montgomery, is even alleged to have purchased one or more of the Subject Drugs.[14] And in Montgomery's case, Plaintiffs merely allege that she was

[13] As an alternative rationale for dismissing Plaintiffs' claims, Schering suggests that Plaintiffs receipt of some value for their drug purchases forestalls their allegations of injury. (Schering Br. at 14.) The Court is not persuaded by this argument. In short, receipt of value cannot have the talismanic effect of insulating defendants absolutely from liability, especially where the value received may be negligible compared to the amount paid for the drugs in question. Instead, the holding in Janssen that injury may be pled by alleging that "[a] drug was inferior on some level and worth less than what [plaintiffs] paid for it[]" is apt.

[14] Plaintiffs allege that individual Plaintiffs Estelle and Hutson and the Bratton Plaintiffs purchased and consumed Eulexin to treat prostate cancer. (See Complaint ¶¶ 17-19.) The Court has previously determined that the class of drugs at issue in this action is limited to the Intron

prescribed and paid for Intron Franchise Drugs, including PEG-Intron and Rebetol, to treat "her medical condition." (Complaint ¶ 16.) Plaintiffs do not identify Montgomery's medical condition. Nor do they allege that Montgomery purchased and consumed PEG-Intron and Rebetol to treat an off-label indication. Most importantly, Plaintiffs do not identify any lower-cost treatments that were available to treat Montgomery's unidentified medical condition. The pleadings of the TPPs are similarly deficient because the TPPs never allege that they purchased Temodar or the Intron Franchise Drugs for off-label use by any of their beneficiaries. (See Plaintiffs' Brief at 7 ("At this early stage, some TPPs lack information to identify precisely which of their beneficiaries took the Subject Drugs for off-label or ineffective uses.").) Without alleging that these TPPs paid for a single off-label use of the Subject Drugs, Plaintiffs cannot logically allege that a physician could have substituted a cheaper, equally effective alternative treatment for the drugs actually prescribed.[15] And even where Plaintiffs do identify alternatives available to treat conditions for which the Subject Drugs were marketed off-label, Plaintiffs claims regarding the relative safety and efficacy of the Subject Drugs vis-a-vis alternatives are wanting. They suggest that, because a drug is not approved by the FDA to treat certain

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Franchise Drugs and Temodar. See Note 3, supra.

[15] Plaintiffs seem to suggest that the Court should assume that TPPs could and would have purchased cheaper alternatives to treat all indications for which the Subject Drugs were prescribed and purchased off-label. Without question, when reviewing a motion to dismiss under Rule 12(b)(6), the Court must "accept all factual allegations in the complaint as true and give the pleader the benefit of all reasonable inferences that can be fairly drawn therefrom." Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir.1993). But because the Complaint is entirely lacking in allegations that there actually were cheaper, equally effective alternative drugs for the off-label indications for which Temodar and the Intron Franchise Drugs were prescribed, the Court will not fill the void by inferring the existence of cheaper alternatives for a variety of medical conditions based on little more than generalized allegations.

indications, the drug is *a fortiori* not as effective or safe as approved treatments. For example, Plaintiffs allege that they were injured when they paid for Temodar to treat GBM and metastatic melanoma off-label rather than cheaper, equally effective alternatives. (Complaint ¶¶ 245-26.) Yet, the Medical Compendia supported Temodar to treat both GBM and metastatic melanoma and the FDA ultimately approved Temodar as safe and effective for GBM.

In sum, Plaintiffs' allegations concerning the availability of cheaper and more effective alternatives to the Subject Drugs are wholly inadequate to support RICO injury. RICO injury of this type may only be pled by alleging that the drugs actually purchased by a plaintiff were "inferior on some level or worth less than what [plaintiff] paid for it." Janssen, 2008 WL 5413105, at *8. The Complaint contains no such allegations. Therefore, to the extent that Plaintiffs' allege that they have suffered a concrete financial loss to business or property because they purchased the Subject Drugs off-label rather than cheaper alternatives, their theory of injury is not cognizable under RICO.

4. Inflated Price of the Subject Drugs

Plaintiffs' final theory of RICO injury is that they paid too much for the Subject Drugs because Schering set "higher, premium prices" based on an "assumption of limited, on-label usage, rather than what would have been a market-determined price reflecting the wider usage for which Defendant Schering illegally marketed the drugs." (Complaint at ¶ 247.) They claim that the prices of Temodar and the Intron Franchise Drugs were artificially inflated by Schering in order to finance the off-label marketing of the Subject Drugs. (Complaint ¶ 248.) Defendants move to dismiss this theory on the argument that the type of injury alleged by Plaintiffs is essentially a fraud-on-the-market theory of damages – a theory which is not cognizable as a

matter of law. (Schering Br. at 16.) Defendants aver that Plaintiffs allege a market-based theory of injury because they cannot "present facts demonstrating actionable injury with respect to any particular prescriptions for which they paid[.]" (Schering Defendants' Reply Brief at 5.) Defendants conclude, therefore, that Plaintiffs have failed to adequately demonstrate an injury for which they may recover. (Id. at 16-17.)

Plaintiffs do not expressly plead a fraud on the market theory of RICO injury, presumably because such a theory has been resoundingly rejected outside the context of federal securities fraud litigation. See, e.g., Williams, 229. F. Supp. 2d at 177; Heindel, 381 F. Supp. 2d at 380; Merck, 192 N.J. at 392. In fact, they specifically disavow any effort to import fraud on the market doctrine to the pricing of prescription drugs. (See Transcript at 21:18-24.) Instead, Plaintiffs suggest that their theory is distinguishable from the classic fraud-on-the-market theory of injury because they do not presume reliance and because, in addition to relying upon statistical proofs, Plaintiffs will offer internal Schering documents in order to tie the off-label promotion of the Subject Drugs to the alleged premium prices paid by consumers and the TPPs. (Pl. Opp. Br. at 9.) In support of this distinction, Plaintiffs rely upon In re Zyprexa, in which Judge Weinstein permitted plaintiffs to allege a price inflation theory of RICO injury where they pled that defendant misrepresented the safety and efficacy of Zyprexa and those misrepresentations "kept demand for Zyprexa at a higher level than it otherwise would have been; elevated demand allowed [defendant] to keep prices higher than they otherwise would have been; and plaintiffs paid more for Zyprexa than they otherwise would have." 493 F. Supp. 2d at 577-78. Furthermore, Plaintiffs suggest that the Third Circuit has approved of a similar price inflation theory of injury in In re Warfarin Sodium Antitrust Litig., 391 F.3d 516 (3d Cir. 2004)

("Warfarin"), where the Court held that plaintiff third party payors suffered antitrust injury when, as a result of defendant's misrepresentations, they "paid supracompetitive prices" for the drug at issue rather than a lower-priced generic. Id. at 531.

While denominated as a premium price or price inflation theory of injury, it is abundantly clear that Plaintiffs' fourth theory of injury is actually a classic fraud-on-the-market theory normally pled in securities fraud cases, but one which is not cognizable under RICO. To plead injury under a fraud-on-the-market theory, a plaintiff need only allege that the price of a drug "was higher than it should have been as a result of defendant's fraudulent marketing campaign[.]" Merck, 192 N.J. at 392. In other words, a plaintiff relies upon a fraud-on-the-market theory when it alleges that "the fact of advertising the products caused the prices to rise both for the ones that are effective and for these, allegedly ineffective products as well." New Jersey Citizen Action v. Schering-Plough Corp., 367 N.J.Super. 8, 15-16 (App. Div. 2003). Here, Plaintiffs expressly claim that misrepresentations made during the course of Schering's off-label marketing plan drove up the market prices of the Subject Drugs and, as a consequence, caused the Plaintiffs to purchase Temodar and the Intron Franchise Drugs at prices higher than they would have paid in the absence of the off-label marketing. Courts have consistently rejected this sort of market-based injury as having no application in the context of claims for recovery of the purchase price for prescription drugs. See, e.g., Prohias, 485, F. Supp. 2d at 1336-37; Williams, 297 F. Supp. 2d at 177. In Heindel v. Pfizer, Inc., this Court rejected an attempt by plaintiffs to recover a portion of a drug's purchase price through a price inflation theory, holding that "there is no prescription drug market, at least as the term is understood in the securities context." 381 F. Supp. at 380. Whereas the price of securities are set by the price at which buyers are willing to buy the

securities and sellers are willing to sell, here, as in Heindel, Plaintiffs' theory of injury relies upon the faulty assumption that the prices of the Subject Drugs fluctuate in a similar manner. See Prohias, 485 F. Supp. 2d at 1337. In reality, the price of prescription drugs are fixed by pharmaceutical manufacturers, not the market. Any perceived price impact attributed to Schering's off-label marketing is merely speculative and discounts the impact of important external variables such as the medical judgment of physicians and the preference of patients.

Plaintiffs' reliance upon In re Zyprexa and Warfarin are unavailing. Notably, In re Zyprexa relied heavily upon Schwab v. Philip Morris, Inc., 449 F. Supp. 2d 992 (E.D.N.Y. 2006), which was subsequently reversed by the Second Circuit in McLaughlin. In McLaughlin, the Second Circuit refused to import a fraud-on-the-market presumption to RICO injury, holding that plaintiffs' "price impact theory...fails as a matter of law" because "a court...would have to engage in a series of speculative calculations to ascertain whether, and in what amount, plaintiffs suffered a loss." 522 F.3d at 230. Were the Court to accept Plaintiffs' price inflation theory, it would have to engage in just the sort of speculation of price effect and economic loss that was scrupulously rejected in McLaughlin. And the Third Circuit's approval of a price inflation theory of injury in Warfarin can be clearly distinguished from this case because, in Warfarin, the Court permitted plaintiffs to assert antitrust injury, not RICO injury, through price inflation. 391 F.3d at 531. Plaintiffs have not set forth any support for the proposition that the amorphous concept of anti-competitive injury in antitrust law is interchangeable with RICO's requirement that injury be directly caused by the predicate acts alleged in the Complaint. Furthermore, Warfarin involved allegations of antitrust violations premised on defendants having disseminated false and misleading information about a lower-priced, but chemically-equivalent, generic drug in order to

entice individuals and TPPs to continue to purchase the branded drug, Coumadin. Id. at 521-22. In this case, Plaintiffs have not identified any cheaper alternatives that were arguably as effective as the Subject Drugs for the named Plaintiffs or their beneficiaries and they certainly do not allege that there were cheaper, chemically-equivalent generic drugs available to consumers and TPPs. Therefore, Warfarin is distinguishable.

The gravamen of Plaintiffs' theory of injury is that they suffered economic loss where the price of the Subject Drugs increased as a result of misrepresentations made by Schering in the off-label promotion of Temodar and the Intron Franchise Drugs. This is, by definition, a fraud-on-the-market theory and one which is not cognizable under RICO.[16] Plaintiffs have not pled a single cognizable theory of RICO injury and, therefore, their RICO claims will be dismissed.

B. Statute of Limitations

Defendants also move to dismiss the bulk of Plaintiffs' RICO and NJRICO claims based on the applicable limitations periods. Plaintiffs' RICO and NJRICO claims are both governed by four year statutes of limitations. See County of Hudson v. Janiszewski, 520 F. 631, 640 (D.N.J. 2007); Matter of Integrity Ins. Co., 245 N.J. Super. 133, 136 (Law Div. 1990). Plaintiffs claim that the facts surrounding the Government's investigation of Schering's alleged off-label promotion became public as early as 2001, and that there was sufficient public information regarding the investigation by November 2002 for the Court to find that the Plaintiffs were or

[16] Plaintiffs' fourth theory of RICO injury is also untenable because Plaintiffs do not differentiate among individual plaintiffs and beneficiaries who received a safe and effective treatment from the Subject Drugs and those who allegedly did not. Therefore, their theory of price inflation would permit *any purchaser* of the Subject Drugs, even those who miraculously recovered from their medical conditions as a result of treatment with the Subject Drugs, to plead injury to their business or property under RICO.

should have been aware of their injury and its source. (Schering Br. at 18.) Moreover, Schering makes light of the Plaintiffs' failure to dispute that the public information concerning the Government's investigation should have put them on notice of their injury and its source. (Schering Reply Br. at 6.)

Schering's statute of limitations argument is unpersuasive. On a motion to dismiss RICO claims, the Defendants bear the burden of proving that plaintiffs have failed to comply with the relevant limitations period. See Gunter v. Ridgewood Energy Corp., 32 F. Supp. 2d 166, 174 (D.N.J. 1998). "Moreover, because 'the applicability of the statute of limitations usually involves questions of fact for the jury,' defendants bear a heavy burden in seeking to establish that there is no genuine issue of material fact and that as a matter of law the [RICO] claims are barred." Id. (quoting Van Buskirk v. Carey Canadian Mines, Ltd., 760 F.2d 481, 498 (3d Cir. 1985)). Nothing on the face of the Complaint establishes conclusively that Plaintiffs knew or should have known the details of the off-label marketing plan and alleged illegal conduct by the date alleged by Defendants. Clearly Plaintiffs were on actual or inquiry notice of facts underlying the alleged frauds when Schering Sales ultimately settled federal criminal and civil charges in August 2006. However, taking the allegations in the Complaint as true, it is not at all clear that the FDA warning letter, public filings and newspaper articles reporting the Government's investigation of Schering's off-label marketing of the Subject Drugs provided warnings sufficient to put Plaintiffs on notice of their purported RICO claims as early as 2002 as alleged by Defendants. In addition, Plaintiffs' allegation that Defendants concealed their illegal conduct raises the possibility that the applicable statutory periods should be tolled and, by implication, creates an additional hurdle to establishing that the RICO claims are barred.

Because there are legitimate questions of fact as to whether the Plaintiffs were on inquiry notice of the conduct and injury underlying their claims and of the alleged concealment by Defendants of their illegal conduct, the Defendants' motion to dismiss Plaintiffs' RICO and NJRICO claims as barred by the applicable statutes of limitations will be denied.

C. Causation

To assert a RICO claim based on mail and wire fraud, a plaintiff must demonstrate that the injury to plaintiff's business or property was caused "by reason of a violation" of RICO. See Sedima, 473 U.S. at 496. To establish causation, a plaintiff is required to show that the RICO violation "not only was a 'but for' cause of his injury, but was the proximate cause as well." Holmes v. Securities Investor Protection Corp., 503 U.S. 258, 268 (1992)("Holmes"). Proximate cause requires "some direct relation between the injury asserted and the injurious conduct alleged." Id.; see also Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 461 (2006) ("When a court evaluates a RICO claim for proximate causation, the central question it must ask is whether the alleged violation led directly to the plaintiff's injuries."). In this case, Plaintiffs contend that causation is readily established because "[h]ad [Schering] not fraudulently expanded the market for its drugs, Plaintiffs would not have had to pay for [the Subject Drugs] at all in some cases, or at such high prices in all cases." (Pl. Opp. Br. at 10.) Defendants move to dismiss the RICO and NJRICO claims on the argument that Plaintiffs have failed to sufficiently allege a causal connection between the alleged RICO violations and any Plaintiff's purported injury. In particular, they suggest that Plaintiffs do not demonstrate a cognizable theory of proving causation. Moreover, Defendants contend that Plaintiffs' causation argument fails because they have not pled the underlying frauds with the particularity required by Rule 9(b), and that even if

they had, Plaintiffs still could not establish the requisite causal connection under RICO.

Plaintiffs propose to demonstrate causation through expert testimony and a statistical analysis of Schering's sales data. (Id. at 11.) As support for offering proofs of this sort, Plaintiffs cite Judge Saras's class certification opinion in Neurontin, 244 F.R.D. 89 (D. Mass. 2007), and In re Zyprexa Prods. Liab. Litig., 493 F. Supp. 2d 571 (E.D.N.Y. 2007). Plaintiffs observe that, in Judge Saras's initial opinion denying class certification in Neurontin, she held that TPP plaintiffs could establish standing to assert RICO claims based on off-label promotion through a "statistical likelihood of payment for a specific indication." (Pl. Br. at 11 (citing Neurontin, 244 F.R.D. at 107).) And in Zyprexa, a case in which plaintiffs proceeded on a price inflation theory of causation similar to that alleged by Plaintiffs in this case, Judge Weinstein denied the defendant's motion for summary judgment on plaintiffs' RICO and consumer fraud claims, finding that plaintiffs had demonstrated a sufficient causal nexus between the defendant's alleged fraud and their own claimed economic injuries. Id. at 576. The district court concluded that plaintiffs could use statistical proof to establish reliance because plaintiffs alleged a "sophisticated, broad-based [scheme, which is] by [its] very nature ... likely to be designed to distort the entire body of public knowledge rather than to individually mislead millions of people[.]" Zyprexa, 493 F.Supp. 2d at 578-79 (citing Schwab v. Phillip Morris, Inc., 449 F. Supp. 2d at 1047, 1115-17). Based on similar rationale, Plaintiffs claim that they have plead and can prove causation.

Notwithstanding Plaintiffs' citation to Desiano and Zyprexa, the Court concludes that the Plaintiffs simply cannot prove causation through generalized proof in this case. Judge Weinstein's conclusion in Zyprexa that RICO causation is susceptible to generalized proof relies

heavily on Desiano and Schwab v. Philip Morris USA, Inc., 449 F. Supp 2d 992 (E.D.N.Y. 2006). As the Court has already explained, Schwab was subsequently reversed in McLaughlin, with the Second Circuit holding that aggregate proof, in the form of increased demand, is not a viable theory for demonstrating RICO causation. Id. at 226. To the extent that Desiano's analysis of causation is still good law – a proposition which is questionable in light of McLaughlin – the Court concludes that Second Circuit's causation analysis in McLaughlin should apply in this case.[17] In stark contrast to the rationale underlying Judge Weinstein's decision in Zyprexa, the Court in McLaughlin held "the issue of loss causation...cannot be resolved by way of generalized proof.... Thus, establishing the first link in the causal chain - that defendants' misrepresentation caused an increase in market demand - would require individualized proof[.]" McLaughlin, 522 F.3d at 226. The Second Circuit reasoned that, "because factors other than defendants' misrepresentation may have intervened and affected the demand and price of Lights, and because determining the portion of plaintiffs' injury attributable to defendants' wrongdoing would require an individualized inquiry, plaintiffs cannot establish loss causation on a class-wide basis." Id. at 227. Here, such an individualized inquiry would require the factfinder to determine which off-label prescriptions were written by doctors (and ultimately paid for by Plaintiffs) as a direct result of Schering's alleged misconduct.

The Second Circuit is not alone in questioning whether RICO causation may be established on an aggregate basis. In Ironworkers Local Union No. 68 & Participating

[17] Notably, the Second Circuit in Desiano analyzed proximate cause under New Jersey law rather than federal law. The Court noted that it was "very much inclined to agree with Plaintiffs" that "the law of New Jersey on proximate cause does not have the relatively narrow directness requirements applied by the federal courts under RICO...." Desiano, 326 F.3d at 349.

Employers Health & Welfare Funds v. Astrazeneca Pharmaceuticals L.P., 585 F. Supp. 2d 1339 (M.D. Fla. 2008), the district court dismissed with prejudice a putative class action by third party payors seeking to recover monies spent on the antipsychotic drug Seroquel as a result of allegedly fraudulent off-label marketing. Relying upon the Supreme Court's decision in Holmes, the court held that the causal nexus between plaintiffs' alleged injury and defendants' off-label marketing was too attenuated. Id. at 1344-45. For the plaintiff third party payors which purchased Seroquel to establish the requisite proximate cause, the court observed that "each physician who prescribed [the Subject Drugs] to an individual consumer or [TPP beneficiary] would have to be questioned as to whether his or her independent medical judgment was influenced by Defendants' misrepresentations, and to what extent.... This is precisely the type of 'intricate, uncertain inquir[y]' the Supreme Court sought to prevent[]" in its decision in Holmes. Id. at 1344 (quoting Anza, 547 U.S. at 460). And in Janssen, Judge Wolfson questioned whether RICO's proximate cause element could ever be satisfied in a case involving allegations by third party payors of fraudulent off-label marketing directed at prescribing physicians, "or if the independent and individualized decision-making of physicians prescribing [a drug] breaks any chain of causation between [d]efendants' alleged misconduct and [p]laintiffs' payment for the medication." Janssen, 2008 WL 543105, at *9 (citing Holmes, 503 U.S. at 268).

Because the Court concludes that these Plaintiffs may not prove causation by way of generalized allegations and aggregate proof, the Court now turns to the allegations contained in the Complaint to determine whether Plaintiffs have adequately pled causation. Where acts of mail and wire fraud constitute the alleged predicate racketeering acts, those acts are subject to the heightened pleading requirement of Rule 9(b) and must be pled with specificity. Rolo, 155 F.3d

657-58. Plaintiffs "need not, however, plead the 'date, place or time' of the fraud, so long as they use an 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.' Id. at 658 (quoting Seville, 742 at 791).

As a review of the Complaint makes clear, Plaintiffs inject only the slightest modicum of precision into their claims. Instead, they make largely vague and conclusory allegations regarding how they were purportedly harmed by Schering's off-label promotion of the Subject Drugs. For instance, Plaintiffs allege that "Schering fraudulently marketed Temodar ... and paid doctors remunerations[,] ... [which] caused third party payors to pay for an increased amount of medication that did not benefit their members[,] ... [and which caused harm to patients] to the extent [they] (sic) paid for treatments that were not safe or effective." (Complaint ¶ 237.) Notably, nowhere in the Complaint, which encompasses 138 pages, do Plaintiffs detail which doctor(s) were paid remunerations, which third party payor(s) paid for Temodar and for what indications they paid, and which patient(s) paid for the Subject Drugs and whether those drugs were prescribed for off-label indications. Rather than individualized allegations delineating with particularity the connection between the injury to business or property and the alleged RICO violation, Plaintiffs' allegations resemble prefabricated claims lacking any detail. Under the pleading requirements of Rule 9(b) and those articulated by the Supreme Court in Ashcroft v. Iqbal and Bell v. Twombly, this sort of pleading is simply insufficient. See Iqbal, 129 S.Ct. at 1949; Twombly, 550 U.S. at 555.

What's more, Plaintiffs summary pleadings ignore reality. Some doctors who prescribed the Subject Drugs for off-label uses may have been influenced by marketing information received from Schering while other physicians who routinely prescribe Temodar and the Intron Franchise

Drugs for unapproved conditions may have never received any information from Schering. Likewise, the extent to which third party payors were influenced to reimburse for the Subject Drugs or to add the drugs to the formularies varies widely from one TPP to the next. Further, while some third party payors may have paid for the Subject Drugs for off-label indications, it is entirely unclear whether those prescriptions were written for patients with gliomas, melanoma, Hepatitis C or for other indications for which the effectiveness of Temodar and the Intron Franchise Drugs is unquestioned in the Complaint. And finally, with respect to the claims asserted by the individual plaintiffs, the Court is left in a state of sheer bewilderment. Of the four individual named Plaintiffs, only one, Montgomery, is even alleged to have been prescribed and paid for any of the Subject Drugs. (See Complaint ¶¶ 16-19.) And even then, Plaintiffs do not identify the condition for which Montgomery was prescribed and purchased PEG-Intron and Rebetol. (See Id. ¶ 16.)

In sum, Plaintiffs' RICO and NJRICO claims fail for lack of causation. The TPP plaintiffs may not establish the requisite proximate cause through aggregate proof or generalized allegations of fraudulent conduct and resulting harm. Instead, a court or jury would have to determine whether each prescribing physician received fraudulent marketing information from the Defendants and whether each physician was influenced to prescribe the Subject Drugs on account of Schering's conduct. This sort of inquiry is impermissible. Moreover, to the extent that the TPPs and/or the individual plaintiffs claim that they have adequately pled a causal nexus between their purported injury and Schering's conduct, not even the most generous reading of the facts alleged in the Complaint would support this theory. The Complaint is full holes. To be fair, Plaintiffs acknowledge the lack of factual heft in the Complaint by stating that "some TPPs

lack information sufficient to identify precisely which of their beneficiaries took the Subject Drugs for off-label or ineffective uses." (Pl. Br. at 7.) The Court recognizes that Plaintiffs have not had the benefit of discovery to develop their claims more fully, but to hold that the sparse factual allegations contained in the Complaint nonetheless satisfy Rule 9(b) would render the rule a nullity. Because Plaintiffs have not adequately plead RICO causation, their RICO claims will be dismissed.

D. Racketeering Activity

Defendants move to dismiss Plaintiffs' RICO and NJRICO claims on the additional basis that Plaintiffs have failed to adequately plead predicate acts of racketeering activity. A "pattern of racketeering activity" must include at least two predicate acts of racketeering activity. 18 U.S.C. § 1961(5); N.J.S.A. § 2C:41-1.d. Plaintiffs have alleged predicate acts consisting of mail and wire fraud as defined by 18 U.S.C. §§ 1341 and 1343, bribery in violation of the New Jersey Commercial Bribery Statute, N.J.S.A. § 2C:41-10, and violations of the Travel Act, 18 U.S.C. § 1952, and the National Stolen Property Act, 18 U.S.C. § 2314.

The lion's share of the allegations contained in the Complaint relate to the off-label marketing and promotion of the Subject Drugs in violation of the mail and wire fraud statutes. To plead mail or wire fraud, a plaintiff must demonstrate "(1) the defendant[s'] knowing and willful participation in a scheme or artifice to defraud, (2) with the specific intent to defraud, and (3) the use of the mails or interstate wire communications in furtherance of the scheme." United States v. Antico, 275 F.3d 245, 261 (3d Cir. 2001). Allegations of mail and wire fraud are reviewed under the heightened pleading standard of Rule 9(b), which requires that the complaint set forth the nature and terms of the alleged fraudulent misrepresentations with considerable

particularity. Plaintiffs must "allege who made a representation to whom and the general content of the misrepresentation," and must also plead the "date, place or time" of the alleged fraudulent conduct or otherwise "inject[] precision and some measure into [the] allegations of fraud." Lum, 361 F.3d at 224. In addition, the averments of mail and wire fraud must be pled "with particularity with respect to what happened to [] specific plaintiff[s]." Rolo, 155 F.3d at 659. In other words, plaintiffs must identify the predicate acts of racketeering that "directly" injure them.

Plaintiffs have plainly failed to plead the predicate acts of racketeering with the specificity required by Rule 9(b). They never once allege that any of the Defendants communicated with any of the individual consumer or third party payor Plaintiffs. There are no allegations that any Plaintiff or representative or agent of the Plaintiffs received information from Defendants regarding the safety or efficacy of Temodar or the Intron Franchise Drugs. The only specific allegations of false statements or fraudulent misrepresentations contained in the Complaint refer to those made by Defendants to third parties, and the fraudulent nature of those statements is doubtful at best.[18] Furthermore, Plaintiffs never specifically allege what happened to them as required under Rolo. There are no particularized allegations of mail or wire fraud involving any of the named Plaintiffs. Instead, Plaintiffs depend upon information gleaned from Schering Sales's guilty plea and sweeping allegations of off-label marketing to suggest that these Plaintiffs were injured as a result of mail or wire fraud perpetrated by Plaintiffs.[19] Under Rule

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[18] See discussion of "Effectiveness of the Subject Drugs," supra., at 20-31.

[19] Generally, the Court will not dismiss a claim for failure to comply with Rule 9(b) where the facts underlying the alleged mail and wire fraud not pled with particularity are those within defendants' exclusive possession. See Craftmatic Secs. Litig. v. Kraftsow, 890 F.2d 628, 645 (3d Cir. 1989). However, Plaintiffs do not aver that the facts required to make out claims for mail and wire fraud are exclusively within the control of the Defendants. Indeed, it appears that

9(b), pleadings of this sort are grossly inadequate.

In addition, Plaintiffs fail to adequately plead alleged violations of the New Jersey Commercial Bribery Statute, the Travel Act and the National Stolen Property Act. While averments not sounding in fraud are not reviewed for the specificity required by Rule 9(b), under the more generous pleading standards prescribed by Rule 8, a complaint must, nevertheless, "contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Iqbal, 129 S.Ct. at 1949 (quoting Twombly, 550 U.S. at 570). Even by the most generous construction of the pleadings, Plaintiffs do not allege any facts to permit the Court to reasonably infer that these Defendants are liable to these Plaintiffs for violations of RICO. Plaintiffs' averments of Travel Act violations, while somewhat more detailed than their pleadings of mail and wire fraud, nonetheless do not connect the Plaintiffs in any way to Defendants' alleged misconduct. Similarly, the Court will not infer that Plaintiffs have adequately pled predicate acts of racketeering for violation of the New Jersey Commercial Bribery Statute when Plaintiffs have not pled one instance in which a physician prescribed the Subject Drugs as a result Schering's misconduct rather than reliance upon independent medical judgment. See Janssen, 2008 WL

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some of the missing facts would be within the control of pharmacy benefit managers and the prescribing physicians. Nonetheless, even if the facts were within the exclusive control of Defendants, Plaintiffs must still describe the efforts they have made to obtain information from the Defendants or third parties. See Zavala v. Wal-Mart Stores, Inc., 393 F. Supp. 2d 295, 314 (D.N.J. 2005)("Even under a more lenient application of Rule 9 . . . the complaint should set forth the nature and scope of plaintiffs' efforts to obtain, before filing the complaint, the information needed to plead with particularity.")(internal citations omitted). They make no such showing.

5413105, at *13. Rather than providing the Court with facts that support the reasonable inference that Defendants' conduct entitles Plaintiffs to relief, the Complaint invites the Court to leap to that conclusion. The Supreme Court recently cautioned that "Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." Iqbal, 129 S.Ct. at 1950. Because Plaintiffs offer no more than conclusory allegations regarding the alleged racketeering activity, the Court concludes that Plaintiffs have failed to adequately plead predicate acts under RICO.

E. RICO Enterprises

Under 18 U.S.C. § 1962(c), it is "unlawful for any person employed by or associated with an enterprise ... to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern or racketeering activity." Under RICO, the definition of enterprise "includes any individual, partnership, corporation, association or other legal entity, an any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). Plaintiffs identify Defendants Schering-Plough Corporation, Kogan, Heiden and Naughton as the liable RICO "person(s)." (See Complaint ¶¶ 20, 281, 301.) Plaintiffs further allege the existence of six (6) separate enterprises: the Schering Sales enterprise and five (5) association-in-fact enterprises involving Schering and ProEd, OCC, Bucom, PIK and the Commitment to Care program. (See RICO Case Statement at 30-37.)

1. The Schering Sales Enterprise

Schering moves to dismiss Plaintiffs' RICO and NJ RICO claims because Plaintiffs allege that Schering-Plough Corporation's wholly owned subsidiary, Schering Sales, is a RICO enterprise. To assert a RICO claim pursuant to § 1962(c), a plaintiff must allege "the existence

of two distinct entities: (1) a 'person'; and (2) an 'enterprise' that is not simply the same 'person' referred to by a different name." Cedric Kushner Promotions Ltd. v. King, 533 U.S. 158, 161 (2001). According to Schering, Plaintiffs' RICO claim fails because Plaintiffs have failed to plead that the RICO person, Schering-Plough Corporation, is sufficiently distinct from the RICO enterprise, an association-in-fact between Schering-Plough Corporation and Schering Sales.

The Third Circuit has repeatedly held that, under § 1962(c), a corporation generally cannot conduct an enterprise consisting of an association-in-fact between the corporation and its wholly owned subsidiary. See, e.g., Gasoline Sales, Inc. v. Aero Oil Co., 39 F.3d 70, 73 (3d Cir. 1994); Lorenz v. CSX Corp., 1 F.3d 1406, 1412 (3d Cir. 1993); Brittingham v. Mobil Corp., 943 F.2d 297, 302-03 (3d Cir. 1991). The Court has explained that such an arrangement is generally not sufficient under RICO because parent corporations and their wholly owned subsidiaries usually share a unity of purpose. See Lorenz, 1 F.3d at 1412. However, the Third Circuit has not entirely foreclosed the possibility of finding that a parent corporation is the person and its subsidiary is the enterprise under 1962(c). Id. In Lorenz, the Court concluded that "it is theoretically possible for a parent corporation to be the defendant and its subsidiary to be the enterprise under section 1962(c)." Id. In order to sustain a RICO claim on such grounds, the plaintiff would have to plead facts which "would clearly show that the parent corporation played a role in racketeering activity which is distinct from the activities of its subsidiary." Id. The Third Circuit has subsequently described the exception to the general rule barring a parent corporation from conducting an enterprise consisting of its subsidiary as "'narrow,' 'theoretical,' and 'rare'." Gasoline Sales, 39 F.3d at 73.

The Court concludes that Plaintiffs have not sufficiently distinguished the role of

Schering Sales from the role played by Schering-Plough Corporation in the alleged off-label marketing scheme. Our jurisprudence tells us that a plaintiff must plead some basis by which the Court could conclude that the parent corporation and its subsidiary played sufficiently distinct roles in the alleged racketeering activity. Lorenz, 1 F.3d at 1412 (citing Glessner v. Kenny, 952 F.2d 702, 710-11 (3d Cir. 1991). But here, Plaintiffs allege that Schering-Plough Corporation and Schering Sales both took part in the alleged conduct that constitute the RICO predicate acts at the heart of this case – bribery and off-label promotion of the Subject Drugs. (See, e.g., Complaint ¶ 287 ("Schering and Schering Sales ... illegally compensated doctors and unlawfully marketed prescription drugs.").) Moreover, in Lorenz, the Third Circuit held that "[a] RICO claim under section 1962(c) is not stated where the subsidiary merely acts on behalf of, or to the benefit of, its parent." Lorenz, 1 F.3d at 1412. Yet, Plaintiffs have specifically alleged that Schering Sales acted at the direction of Schering-Plough Corporation. (See, e.g., Complaint ¶ 285 ("Schering caused its subsidiary, Schering Sales, to market drugs for uses that were not proven to be safe and effective to the FDA and also paid doctors to influence their prescribing decisions.").) Plaintiffs attempt in vain to distinguish the role played by Schering Sales by pleading that "[Schering-Plough Corporation] used the separate corporate identity of Schering Sales to avoid the full consequences of its own criminal actions" and "caused Schering Sales to plead guilty to making false statements to the federal government so that Defendant [Schering-Plough Corporation] could continue to do business with government entities." (Id. ¶ 286.) Yet, the allegation that Schering Sales pled guilty at the behest of Schering-Plough Corporation for Schering-Plough Corporation's benefit is not sufficient to establish that the parent corporation "had a role in the racketeering activity that was distinct from the undertakings of those acting on

its behalf." Gasoline Sales, 39 F.3d at 73 (quoting Brittingham, 943 F.2d at 302). Rather, the suggestion that the subsidiary pled guilty in order to shield Schering-Plough Corporation from liability only strengthens the Court's conclusion that Schering Sales acted on behalf of its parent, with the primary purpose of furthering Schering-Plough Corporation's objectives. See Gasoline Sales, 39 F.3d at 73.

Because Plaintiffs have failed to sufficiently plead a distinction between Schering-Plough Corporation and Schering Sales, Plaintiffs' theory of RICO liability premised on Schering Sales's status as a RICO enterprise fails.[20]

2. The Associations-In-Fact

Plaintiffs plead the existence of five association-in-fact enterprises comprised of Schering-Plough Corporation and each of the four marketing firms and of Schering and the Commitment to Care program. The Supreme Court has described an "association-in-fact" enterprise as "a group of persons associated together for the common purpose of engaging in a course of conduct" and as an "ongoing organization, formal or informal [with] various associates function[ing] as a continuing unit." United States v. Turkette, 452 U.S. 576, 583 (1981). The Third Circuit has construed Turkette to require: (1) proof of an ongoing organization, (2) proof

[20] Plaintiffs suggest that, contrary to the federal RICO statute, a corporate defendant need not be distinct from the alleged enterprise under the New Jersey RICO statute. (Pl. Br. at 18 n.16.) Yet, there appears to be at least some disagreement among New Jersey courts regarding whether a defendant may also be an enterprise under the statute. Compare Maxim Sewerage v. Monmouth Ridings, 273 N.J. Super. 84, 95-96 (Law Div. 1993) (no distinctiveness required between person and enterprise) with State v. Kuklinski, 234 N.J. Super. 418, 421-22 (Law Div. 1988) (terms "employed by and "associated with" contemplate a person distinct from the enterprise). Because the Court ultimately dismisses Plaintiffs NJ RICO claims for failure to adequately plead injury and causation, the Court will not predict whether the New Jersey Supreme Court would hold that a corporate defendant could be both the "person" and the "enterprise" under the NJ RICO statute.

that the associates function as a continuing unit, and (3) proof that the enterprise is an "entity separate and apart from the pattern of activity in which it engages." United States v. Pelullo, 964 F.2d 193, 211 (3d Cir. 1992) (citing United States v. Riccobene, 709 F.2d 214, 221-24 (3d Cir. 1983). "Under the rules of notice pleading, a plaintiff need not specifically allege in her complaint the facts necessary to establish these three enterprise elements." Freedom Medical Inc. v. Gillespie, 2007 WL 2480056, at *9 (E.D. Pa. Aug. 29, 2007) (citing Seville, 742 F.2d at 790); see also Darrick Enters. v. Mitsubishi Motors Corp., 2007 WL 2893366, at *7 (D.N.J. Sept. 28, 2007). However, the allegations contained in the Complaint must not affirmatively negate any of the requisite enterprise elements and must allege facts sufficient to allow the existence of the three Riccobene elements to be inferred. See Seville, 742 F.2d at 790 n. 5 ("[Plaintiff] has affirmatively negated the existence of the third Riccobene factor ... [and] has precluded itself at trial from proving that the four defendants ... formed an enterprise."); Lorenz, 1 F.3d at 1412 (Plaintiffs alleging an association-in-fact between parent and subsidiary corporations "must plead facts which, if assumed to be true, would clearly show that the parent corporation played a role ... distinct from its subsidiary.").

Defendants argue that Plaintiffs have failed to allege facts to support the inference that there was any sort of decision-making structure independent of regular business practices. Further, they contend that the relationships between Schering and each of the marketing firms were little more than customary contractual relationships in which the firms promoted the Subject Drugs. Notwithstanding these arguments, the Court concludes that Plaintiffs have clearly met the burden of pleading the existence of four association-in-fact enterprises comprised of Schering and each of the marketing firms. The Complaint plainly alleges that Schering and

the marketing firms had significant communications regarding the off-label promotion of the Subject Drugs. Plaintiffs also plead that Schering worked in concert with the respective marketing firms to devise various promotional programs, including Continuing Medical Education (CME) conferences, advisory board meetings, and the publication of medical literature, all of which were carried out by Schering and the firms. Moreover, Plaintiffs' allegations are sufficiently specific as to the role played by each of enterprises in marketing Temodar and the Intron Franchise Drugs for the Court to infer that Plaintiffs could, at trial, prove that each enterprise actually exists. (Complaint ¶¶ 210-24.) It can be fairly implied that Plaintiffs allege that the four marketing entities were used to disseminate misrepresentations and bribes in furtherance of Schering's alleged off-label marketing scheme. As such, Plaintiffs have sufficiently pled the existence of the Schering-ProEd, Schering-OCC, Schering-Bucom and Schering-PIK enterprises.

Whether Plaintiffs have sufficiently identified the alleged association-in-fact enterprise comprised of Schering and Documedics/Commitment to Care ("CTC") is another matter.[21] Defendants argue that Plaintiffs have improperly alleged the existence of an enterprise comprised of Schering and CTC, a program used to promote the Subject Drugs off-label. Schering contends that this enterprise fails because CTC is not alleged to be a natural person or legal entity within the meaning of the RICO statute and because associations-in-fact must "have an existence 'separate and apart from the pattern of activity in which it engages,'" which the CTC program

[21] Plaintiffs refer to the CTC program as being managed by a third party entity, Documedics, which was allegedly controlled by Schering. However, the preponderance of the allegations regarding the program describe a relationship between Schering and the CTC program, not Documedics. Therefore, the Court concludes that Plaintiffs have actually pled an association-in-fact enterprise comprised of Schering and the CTC program.

does not have. (Schering Br. at 30 (quoting Riccobene, 709 F.2d at 221).) Plaintiffs assert that, through the CTC program, Schering promoted off-label use of the Subject Drugs by covering the out-of-pocket costs related to Temodar and Intron Franchise prescriptions. The RICO statute, however, requires that an enterprise, by definition, is limited to "any individual, partnership, corporation, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4). The CTC program is none of these. Rather, it is a promotional program, similar to the CME conferences, which purportedly served as a means for promoting the Subject Drugs. Therefore, because a promotional program cannot take part in an enterprise under the definitions prescribed by the RICO statute, the Schering-CTC enterprise is plainly impermissible.[22]

II. Plaintiffs' New Jersey Consumer Fraud Act Claim

Defendants also move to dismiss Plaintiffs' claim brought pursuant to the New Jersey Consumer Fraud Act, N.J.S.A. §§ 56:8-1, *et seq.*, on multiple grounds. In addition to claiming that Plaintiffs have failed to plead cognizable theories of injury and causation under the NJCFA, Defendants assert that the Act was never intended and does not apply to prescription pharmaceuticals. (Schering Br. at 33-35.) In the alternative, assuming that the Court concludes that the NJCFA may be applied to pharmaceuticals, Defendants posit that third party payors are not "consumers" entitled to sue under the NJCFA. (Id. at 36.)

In order to assert a claim under the NJCFA, a plaintiff must allege each of three elements: "(1) unlawful conduct by defendant[s]; (2) an ascertainable loss by plaintiff[s]; and (3) a causal

[22] The Court reaches the same result taking into account the NJ RICO statute's broader definition of enterprise. See N.J.S.A. 2C:41-1(c).

relationship between the unlawful conduct and the ascertainable loss." Bosland v. Warnock Dodge, Inc., 197 N.J. 543, 557 (2009). The Court has previously concluded with respect to Plaintiffs' RICO and NJRICO claims that Plaintiffs may not prove RICO injury and causation through a price inflation theory. The New Jersey Supreme Court has likewise rejected a plaintiff's attempt to use statistical analysis of price effect in place of particularized factual allegations to establish ascertainable loss or causation under the NJCFA. See Int'l Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co., Inc., 192 N.J. 372, 392 (2007) ("Merck") ("To the extent that plaintiff intends to rely on a single expert to establish a price effect in place of a demonstration of an ascertainable loss or in place of proof of a causal nexus between defendant's acts and the claimed damages, however, plaintiff's proofs would fail.").[23] Plaintiffs do not allege an alternative theory of demonstrating ascertainable loss which is cognizable under the NJCFA. Therefore, the Court will dismiss Plaintiffs' NJCFA for failure to properly plead an ascertainable loss. Moreover, Plaintiffs' NJCFA claims also fail for lack of causation. As the Court previously concluded with respect to Plaintiffs' RICO claims, Plaintiffs simply have not established that their purported injuries were proximately caused by Defendants'

[23] The Court is unpersuaded by Plaintiffs' attempts to distinguish the proofs offered by plaintiffs in Merck from those which they propose here. Plaintiffs contend that they will establish cognizable injury by "rely[ing] on several experts and on [Schering's] own internal marketing documents." (Pl. Br. at 9.) In Merck, plaintiffs sought to prove causation and ascertainable loss through the presentation of expert testimony demonstrating that the price of Vioxx was inflated as a result of the marketing conduct at issue. There appears to be no difference between what plaintiffs in Merck sought to prove and what Plaintiffs allege in this case. In short, it is not the nature of the proofs, it is the theory being espoused that is definitive. Here, Plaintiffs could offer the testimony of not one but ten experts, all of whom conclude that Schering's marketing activities inflated the price of the Subject Drugs. But so long as Plaintiffs offer aggregate proof of ascertainable loss and causation in lieu of specific facts establishing a connection between Plaintiffs' purported injury and Schering's alleged misconduct, their NJCFA claims will be dismissed.

alleged illegal conduct.

Because the Court dismisses Plaintiffs' NCFA claims for failure to properly plead injury and causation, it does not address Defendants' argument that the NJCFA does not apply to heavily regulated industries such as the pharmaceutical industry. However, to the extent that Defendants argue that the Plaintiff TPPs are not consumers entitled to sue under the NJCFA, the Court is persuaded that the Third Circuit's decision in J & R Ice Cream Corp. v. Cal. Smoothie Licensing Corp., 31 F.3d 1259, 1273 (3d Cir. 1994)("California Smoothie"), suggests that Defendants are indeed correct.[24] While the term "consumer" is most often associated with an individual purchaser, the NJCFA has been interpreted to afford protection to corporate and commercial entities who purchase goods and services for use in their business operations. See, e.g., Coastal Group, Inc. v. Dryvit Systems, Inc., 274 N.J. Super. 171 (App. Div. 1994); City Check Cashing, Inc. v. Nat'l State Bank, 244 N.J. Super. 304, 309 (App. Div. 1990)(stating that the NJCFA "does not exclude business entities from its protection so long as they are 'consumers'"). In California Smoothie, the Third Circuit acknowledged that the NJCFA's definition of "person" includes business entities. 31 F.3d at 1273 ("a corporation may qualify as a person under the Act when it finds itself in a consumer oriented situation"). In determining whether the sale of a franchise fell within the reach of the NJCFA, the Court of Appeals

[24] It is the obligation of this Court to apply New Jersey law as established by the State's highest court, where the court has spoken. The New Jersey Supreme Court flagged the issue of whether TPPs could sue under the NJCFA in Merck, but expressly declined to decide the issue. 192 N.J. at 377 n.1. In the absence of a definitive statement of the law by the Supreme Court, this Court is required to predict how that court would rule if presented with an issue. The Court follows, and indeed is bound by, the Third Circuit's prediction of New Jersey law in California Smoothie. However, the Court notes that a subsequent decision of the New Jersey Appellate Division in Kavky v. Herbalife Int'l of America, 359 N.J. Super. 497, 501-03 (App. Div. 2003) expressly rejects the Third Circuit's rationale for determining the scope of the NJCFA.

explained that "it is the character of the transaction rather than the identity of the purchaser which determines if the Consumer Fraud Act is applicable." Id. at 1273-74. In this case, the TPPs purchased drugs from the Defendants for use by their beneficiaries or reimbursed beneficiaries for purchases of Schering pharmaceuticals. TPPs do not purchase drugs for their own use or consumption. Rather, they contract with beneficiaries to receive a stream of payments which, in turn, obligates them to pay for all or part of the cost of drugs prescribed to and purchased by their beneficiaries.

Products and services that are purchased for consumption or use in the operation of a business are covered by the NJCFA. See, e.g., Naprano Iron & Metal, 79 F.Supp.2d at 509 (finding the purchase of a crane for use in construction covered by the NJCFA); Hundred East Credit Corp., 212 N.J.Super. at 355-57 (NJCFA covered claims by business related to purchase of computer peripherals). However, "to be a consumer respecting the transaction in question, the business entity must be 'one who uses [economic] goods, and so diminishes or destroys their utilities.'" City Check Cashing, 244 N.J. Super. at 309 (quoting Hundred East Credit Corp. v. Eric Schuster, 212 N.J.Super. 350, 355 (App. Div. 1986), certif. den. 107 N.J. 60 (1986)). The Third Circuit in California Smoothie held that the purchase and sale of a franchise was not covered by the NJCFA because "[franchises] are never purchased for consumption, [but rather]...for the present value of the cash flows they are expected to produce in the future." 31 F.3d at 1274. As the Court has noted, here the TPP Plaintiffs do not use or consume the drugs they purchase. See In re Rezulin Prods. Liab. Litig., 392 F. Supp. 2d 597, 616-17 (S.D.N.Y. 2005) (plaintiff health insurer "was not a consumer of prescription drugs [under the NJCFA]" where plaintiff did not "in some sense benefit[] from the use of the good or service in

question."). Rather, they essentially serve as middlemen or insurers, paying all or part of the cost of a beneficiary's drugs in return for a stream of payments from the beneficiary. See In re Managed Care Litig., 298 F. Supp. 2d 1259, 1303-04 (S.D. Fla. 2003) ("the Provider Plaintiffs cannot be considered 'consumers' by any interpretive stretch of the New Jersey Act. Plaintiffs receive a 'stream of income' for their services and they do not use or consume any economic goods or services offered for sale by Defendants."). For these reasons, the Court concludes that the third party payor Plaintiffs are not consumers entitled to sue under the NJCFA.

Because Plaintiffs have failed to plead causation and ascertainable loss under the NJCFA, and because the TPP Plaintiffs are not consumers entitled to sue under the NJCFA, the Court will dismiss Plaintiffs' NJCFA claim.

III. Common Law Fraud and Negligent Misrepresentation

To state a claim for fraud under New Jersey law, a plaintiff must allege (1) a material misrepresentation of fact; (2) knowledge or belief by the defendant of its falsity; (3) intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damage. Gennari v. Weichert Co. Realtors, 148 N.J. 582, 610 (1997). To establish a claim of negligent misrepresentation, a plaintiff must prove that an incorrect statement was negligently made and justifiably relied upon to recover damages for economic loss or injury sustained as a consequence of that reliance. H. Rosenblum, Inc. v. Adler, 93 N.J. 324, 334 (1983); Gross v. Johnson & Johnson-Merck Consumer Pharms. Co., 303 N.J.Super. 336, 344 (Law Div. 1997). The strict pleading requirements of Rule 9(b) apply to these claims.

Plaintiffs fraud and negligent misrepresentation claims do not meet the stringent requirements for pleading fraud under Rule 9(b). Plaintiffs do not state with the requisite

particularity the circumstances of the alleged fraud or otherwise inject precision into their allegations. As has the Court has already discussed, Plaintiffs make sweeping allegations concerning Defendants' alleged off-label promotion of the Subject Drugs. Yet, Plaintiffs do not plead a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe one of the Subject Drugs to Plaintiffs. In fact, the only colorable allegations by Plaintiffs of receipt and reliance concern the generic allegations, repeated throughout the Complaint, that unnamed doctors, not Plaintiffs, relied on Schering's misrepresentations in prescribing the Subject Drugs to unnamed patients. Plaintiffs cannot argue indirect reliance in this case because the relevant jurisprudence tells us that indirect reliance in the context of fraud requires that, where a plaintiff has not actually received and considered an alleged fraudulent misrepresentation, he must prove that he was at least an intended recipient of the misrepresentation. See Eli Lilly & Co. v. Roussel Corp., 23 F. Supp. 2d 460, 493 (D.N.J. 1998); Port Liberte Homeowners Association, Inc. v. Sordoni Construction Co., 393 N.J.Super. 492, 508 (App. Div. 2007) ("[A] plaintiff must prove that he or she was an intended recipient of the defendant's misrepresentations" in order to assert a claim for fraud.). Similarly, to assert a claim for negligent misrepresentation based on indirect reliance, Plaintiffs must show that they were reasonably foreseeable recipients of Schering's alleged misrepresentations. See Karu v. Feldman, 119 N.J. 135, 146-47 (1990). Plaintiffs have not pled that any Plaintiff received and relied on the alleged misrepresentations. Nor do they allege that Schering intended that any of the Plaintiffs receive the alleged misrepresentations or that it was reasonably foreseeable that they would receive and rely on Schering's statements. Therefore, as a matter of law, they cannot

assert claims for fraud and negligent misrepresentation against Defendants.

Plaintiffs' common law fraud and negligent misrepresentation claims fail for the additional reason that Plaintiffs have not established a causal connection between Plaintiffs' alleged injury and Schering's conduct. Under New Jersey law, it is well established that any injury allegedly sustained by a plaintiff must have been proximately caused by a defendant's conduct. See McCabe v. Ernst & Young, LLP, 494 F.3d 418, 438 (3d Cir. 2007)(noting that "proximate causation is a required element of both common law fraud and misrepresentation under New Jersey law."); Konover Const. Corp. v. East Coast Const. Servs. Corp., 420 F. Supp. 2d 366, 370 (D.N.J. 2006)("Both negligent and fraudulent misrepresentation require a plaintiff to demonstrate that it sustained an injury that was caused by defendant's misrepresentation as an element of the claims."). Based on the foregoing, Defendants' motion to dismiss the common law fraud and negligent misrepresentation claims will be granted.

IV. Plaintiffs' Unjust Enrichment and Equitable Accounting Claims

Defendants move to dismiss Plaintiffs' claims for unjust enrichment and equitable accounting based on the absence of an underlying wrong. (Schering Brief at 39.) Plaintiffs respond that the Defendants ignore a clear underlying wrong - the acts which spawned Schering's guilty plea in the Government's criminal investigation. Moreover, they assert that claims for unjust enrichment and equitable accounting are necessary in the event that "Plaintiffs' legal remedies fail to fully compensate them for the losses incurred[.]" (Plaintiffs' Brief at 39.)

The Court has already concluded that, under the federal RICO statute and New Jersey state law, Plaintiffs have not established injury or ascertainable loss. Furthermore, the Court has held that, even if Plaintiffs had sufficiently alleged injury or ascertainable loss, the injury or loss

is simply too remote and attenuated to establish the causation element required to sustain Plaintiffs' claims. The remoteness of the alleged injury to Defendants' actions also dooms Plaintiffs' unjust enrichment claim. In Steamfitters Local Union No. 420 Welfare Fund v. Phillip Morris, Inc., 171 F.3d 912 (3d Cir. 1999), the Third Circuit observed that "[i]n the tort setting, an unjust enrichment claim is essentially another way of stating a traditional tort claim." Id. at 936. In affirming the district court's dismissal of plaintiffs' unjust enrichment claim, the Court held that "[w]e can find no justification for permitting plaintiffs to proceed on their unjust enrichment claim once we have determined that the District Court properly dismissed the traditional tort claims because of the remoteness of plaintiffs' injuries to defendants' wrongdoing." Id. at 937. Plaintiffs' citation to In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517 (D.N.J. 2004)("K-Dur"), is unpersuasive. In K-Dur, the district court denied defendant's motion to dismiss plaintiffs' unjust enrichment claim and held that the "critical inquiry is whether the plaintiff's detriment and the defendant's benefit are related to, and flow from, the challenged conduct." Id. at 544. K-Dur is clearly distinguishable because, in that case, Judge Greenaway explicitly concluded that he would not consider whether plaintiffs established injury-in-fact, and thus standing, prior to determining class certification. Id. at 544. Here, in contrast, the Court has already held that these Plaintiffs have neither pled a cognizable injury nor a direct relation between Plaintiffs' injury and Schering's alleged misconduct. In addition, to the extent that the facts in K-Dur are analogous to those pled here, the Court notes that the case was decided four years prior to Merck, the case in which the New Jersey Supreme Court determined that injury and causation cannot be established by market-based proofs of the nature offered by Plaintiffs.

For the foregoing reasons, Plaintiffs unjust enrichment and equitable accounting claims

will be dismissed.

V. Civil Conspiracy

Plaintiffs assert a claim for civil conspiracy based on the allegation that they paid for additional prescriptions of the Subject Drugs as the proximate result of Defendants having entered into agreements with third party marketers and doctors to illegally promote the drugs off-label. (Complaint ¶¶ 326-31.) In New Jersey, a claim for civil conspiracy requires a showing of "a combination of two or more persons acting in concert to commit an unlawful act, or to commit a lawful act by unlawful means, the principal element of which is an agreement between the parties to inflict a wrong against or injury upon another, and an overt act that results in damage." Morgan v. Union County Bd. of Chosen Freeholders, 268 N.J.Super. 337, 364 (App. Div. 1993), (quoting Rotermund v. U.S. Steel Corp., 474 F.2d 1139, 1145 (8th Cir. 1973)(internal quotations omitted)). Most importantly, the "gist of the claim is not the unlawful agreement, 'but the underlying wrong which, absent the conspiracy, would give a right of action.'" Morgan, 268 N.J. Super. at 364 (quoting Bd. of Educ. v. Hoek, 38 N.J. 213, 238 (1962)). In this case, the only underlying wrong that has been pled by Plaintiffs is that Defendants marketed the Subject Drugs off-label in violation of the FDCA. As the Court has previously made clear, there is no private right of action for violations of the FDCA. In the absence of an underlying right of action for the facts alleged in the Complaint, Plaintiffs cannot assert a claim for civil conspiracy. Therefore, Plaintiffs' claim will be dismissed.

VI. Aiding and Abetting a Breach of Fiduciary Duty

The Individual Plaintiffs assert claims against Defendants for aiding and abetting a breach of fiduciary duty based on alleged bribes paid by Defendants to influence doctors to prescribe the

Subject Drugs. Yet, Plaintiffs again offer little more than generalizations and overbroad allegations of a so called scheme of bribery. The Complaint is completely barren of any allegations that the Individual Plaintiffs' physicians had even been contacted by Defendants regarding the Subject Drugs, never mind that Defendants had engaged in the sort of interaction that would give rise to allegations of bribery and associated claims for breach of a fiduciary duty. The Court is convinced that this claim should be dismissed along with the other claims based on Plaintiffs' failure to articulate facts with any degree of specificity to support their claim that Defendants aided the Individual Plaintiffs' doctors in breaching their fiduciary duty to their patients. Therefore, this count will be dismissed.

VII. Motion to Dismiss Filed by the Individual Defendants

The Individual Defendants have separately moved to dismiss the claims asserted against them [Docket Entry No. 141]. Plaintiffs claims against Defendants Kogan, Heiden and Naughton suffer from even graver factual deficiencies in pleading than the claims asserted against the Schering Defendants. Based on this, and for many of the same reasons stated above, the Court will also dismiss the claims asserted against Defendants Richard J. Kogan, William K. Heiden and Mary Naughton.

CONCLUSION

For the many reasons stated above, the motions to dismiss filed by the Schering Defendants and the Individual Defendants will be granted and the Complaint must be dismissed. Where, as here, a complaint is dismissed pursuant to Federal Rule 12(b)(6) for failure to state claims upon which relief may be granted, a plaintiff should be granted the opportunity to amend her complaint unless amendment would be inequitable or futile. Grayson v. Mayview State

Hosp., 293 F.3d 103, 106 (3d Cir. 2002). The Court grants Plaintiffs leave to file an amended complaint with the proviso that they must allege, with the specificity required by Rule 9(b) of the Federal Rules of Civil Procedure, that Defendants violated RICO and the NJCFA by fraudulently misrepresenting the safety and efficacy of the off-label uses of Temodar and the Intron Franchise Drugs. An amended complaint should not rely upon allegations that Defendants engaged in the off-label promotion of the Subject Drugs or other factual or legal arguments previously put forth by Plaintiffs and addressed by the Court in the instant motion.

s/ Stanley R. Chesler

STANLEY R. CHESLER, U.S.D.J.

Dated: July 10, 2009